

Health Care General Committee

Wednesday, March 15, 2006 9:00 AM - 11:00 AM 306 HOB

Revised

COMMITTEE MEETING PACKET



AGENDA

Health Care General Committee March 15, 2006 9:00 a.m. – 11:00 a.m. 306 HOB

- I. Call to order/Roll Call
- II. Opening Remarks
- III. Consideration of the following bill:
 - HB 621 - Health Maintenance Organizations by Grimsley
- IV. Presentation by the Florida Council for Community Mental Health Mental Health and Hospital Emergency Care
- V. Presentation by the Department of Health Crohn's Disease and Ulcerative Colitis Report
- VI. Closing Remarks and Adjournment

A bill to be entitled

An act relating to health maintenance organizations; amending s. 641.316, F.S.; redefining the term "fiscal intermediary services organization"; amending s. 641.234, F.S.; expanding the requirement that a health maintenance organization remains responsible for violations of certain statutory requirements if the organization transfers to any entity the obligations to pay any provider for claims arising from services to subscribers of the organization; amending s. 626.88, F.S., relating to the regulation of insurance administrators; conforming provisions to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (b) of subsection (2) of section 641.316, Florida Statutes, is amended to read:

641.316 Fiscal intermediary services.--

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(b) The term "fiscal intermediary services organization" means a person or entity that which performs fiduciary or fiscal intermediary services to health care professionals who contract with health maintenance organizations other than a fiscal intermediary services organization owned, operated, or controlled by a hospital licensed under chapter 395, an insurer licensed under chapter 624, a third-party administrator licensed under chapter 626, a prepaid limited health service organization licensed under chapter 636, a health maintenance organization

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licensed under this chapter, or physician group practices as defined in s. 456.053(3)(h) and providing services under the scope of licenses of the members of the group practice.

Section 2. Subsection (4) of section 641.234, Florida Statutes, is amended to read:

641.234 Administrative, provider, and management contracts.--

- (4)(a) If a health maintenance organization, through a health care risk contract, transfers to any entity the obligations to pay any provider for any claims arising from services provided to or for the benefit of any subscriber of the organization, the health maintenance organization remains shall remain responsible for any violations of ss. 641.3155, 641.3156, and 641.51(4). The provisions of ss. 624.418-624.4211 and 641.52 shall apply to any such violations.
 - (b) As used in this subsection, ÷
- 1. The term "health care risk contract" means a contract under which an entity receives compensation in exchange for providing to the health maintenance organization a provider network or other services, which may include administrative services.
- 2. the term "entity" means a person licensed as an administrator under s. 626.88 and does not include any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the members of the group practice. The term does not include a hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the

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57 scope of its license.

Section 3. Subsection (1) of section 626.88, Florida Statutes, is amended to read:

626.88 Definitions.--For the purposes of this part, the term:

- (1) "Administrator" is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage or coverage of any other expenses described in s. 624.33(1) or any person who, through a health care risk contract as defined in s. 641.234 with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers, other than any of the following persons:
- (a) An employer or wholly owned direct or indirect subsidiary of an employer, on behalf of such employer's employees or the employees of one or more subsidiary or affiliated corporations of such employer.
 - (b) A union on behalf of its members.
- (c) An insurance company which is either authorized to transact insurance in this state or is acting as an insurer with respect to a policy lawfully issued and delivered by such company in and pursuant to the laws of a state in which the insurer was authorized to transact an insurance business.
 - (d) A health care services plan, health maintenance

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organization, professional service plan corporation, or person in the business of providing continuing care, possessing a valid certificate of authority issued by the office, and the sales representatives thereof, if the activities of such entity are limited to the activities permitted under the certificate of authority.

- (e) An entity that is affiliated with an insurer and that only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed insurance business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the insurance commissioner, upon a request from the insurance commissioner. For purposes of this paragraph, the term "insurer" means a licensed insurance company, health maintenance organization, prepaid limited health service organization, or prepaid health clinic.
- (f) A nonresident entity licensed in its state of domicile as an administrator if its duties in this state are limited to the administration of a group policy or plan of insurance and no more than a total of 100 lives for all plans reside in this state.
- (g) An insurance agent licensed in this state whose activities are limited exclusively to the sale of insurance.
- (h) A person licensed as a managing general agent in this state, whose activities are limited exclusively to the scope of activities conveyed under such license.
 - (i) An adjuster licensed in this state whose activities

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are limited to the adjustment of claims.

- (j) A creditor on behalf of such creditor's debtors with respect to insurance covering a debt between the creditor and its debtors.
- (k) A trust and its trustees, agents, and employees acting pursuant to such trust established in conformity with 29 U.S.C. s. 186.
- (1) A trust exempt from taxation under s. 501(a) of the Internal Revenue Code, a trust satisfying the requirements of ss. 624.438 and 624.439, or any governmental trust as defined in s. 624.33(3), and the trustees and employees acting pursuant to such trust, or a custodian and its agents and employees, including individuals representing the trustees in overseeing the activities of a service company or administrator, acting pursuant to a custodial account which meets the requirements of s. 401(f) of the Internal Revenue Code.
- (m) A financial institution which is subject to supervision or examination by federal or state authorities or a mortgage lender licensed under chapter 494 who collects and remits premiums to licensed insurance agents or authorized insurers concurrently or in connection with mortgage loan payments.
- (n) A credit card issuing company which advances for and collects premiums or charges from its credit card holders who have authorized such collection if such company does not adjust or settle claims.
- (o) A person who adjusts or settles claims in the normal course of such person's practice or employment as an attorney at

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law and who does not collect charges or premiums in connection with life or health insurance coverage.

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- (p) A person approved by the department who administers only self-insured workers' compensation plans.
- (q) A service company or service agent and its employees, authorized in accordance with ss. 626.895-626.899, serving only a single employer plan, multiple-employer welfare arrangements, or a combination thereof.
- (r) Any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the member of the group practice.
- (s) Any hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

A person who provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers shall comply with the provisions of ss. 627.6131, 641.3155, and 641.51(4).

Section 4. This act shall take effect October 1, 2006.

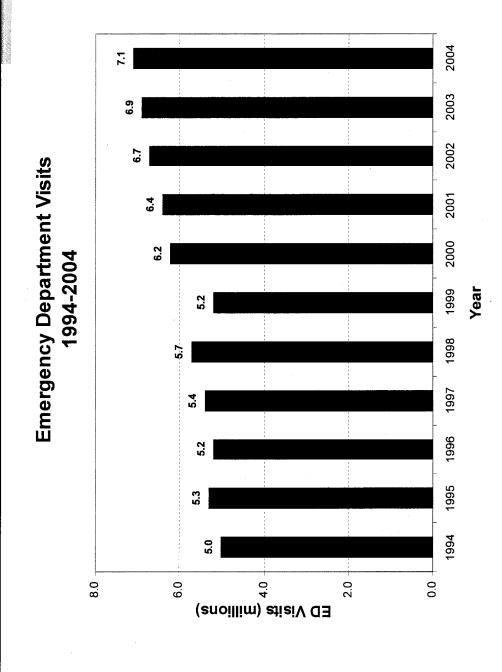
Emergency Psychiatric Care A Community Crisis

House Health Care Committee March 15, 2006 Florida Council

Emergency Department (ED) Use The Facts

- In 2004, there were 7.1 million ED visits in Florida; 1.3 million resulted in hospital admissions (AHCA, 2006).
- From 1994 to 2003, visits increased by 26.2% in the U.S. (AHCA, 2006).
- Between 1994-2004, the number of ED visits in Florida increased by 40.9%, while there was a 5.3% decrease in the number of EDs (AHCA, 2006).
- Accounting for increases in population, the visit rate per 1,000 persons increased by 12.9% over the same period (AHCA, 2006).

Florida Emergency Department Visits



Source AHCA Hospital Financial Database

Emergency Department (ED) Use The Facts

- million]; the average charge per visit was \$619 In 2004, total ED charges in Florida were \$4.4 billion, a 457.0% increase from 1994 [\$791 (AHCA, 2006).
- The average ED wait time in Florida is 3 hours (AHCA, 2006); half of ED patients nationally spend 2-6 hours in the ED (CDC, 2005).
- Florida: 7.82 47th in the nation (ACEP, 2006). The number of EDs per 1 million people in
- Florida's rank on access to emergency care: C-[41st in nation] (ACEP, 2006); overall Florida EDRank: C- (ACEP, 2006).
- Nationally, 62% of emergency departments are at or over capacity; one-half of urban EDs are at over capacity (AHCA, 2002).

Emergency Department (ED) Use Psychiatric Disorders

- abuse disorders constitutes a significant and ED use by those with psychiatric/substance growing burden on hospital EDs.
- Two million people visited EDs for psychiatric care in the U.S. in 2002 (NCHS, 2003).
- Many hospital EDs are ill equipped to meet the because of inadequate numbers of psychiatric practitioners and beds in many EDs. needs of patients with psychiatric disorders
- Nationally, from 1992 to 2001, mental health-related ED visits increased from 4.95 to 6.3% of total ED visits and increased from 17.1 to 23.6 visits per 1,000 population (Larkin et al, 2005).

Emergency Department (ED) Use Psychiatric Disorders

- In a 2004 survey conducted by the American College of Emergency Physicians, 60% of physicians reported that the increase in psychiatric ED patients is:
- negatively affecting access to emergency medical care for all patients;
- causing longer wait times;
- fueling patient frustration;
- limiting the availability of hospital staff; and
- decreasing the overall availability of ED beds (ACEP, 2006).
- Two-thirds of emergency physicians attribute the recent escalation of psychiatric patients to budget cutbacks and the decreasing number of psychiatric beds (ACEP, 2006).

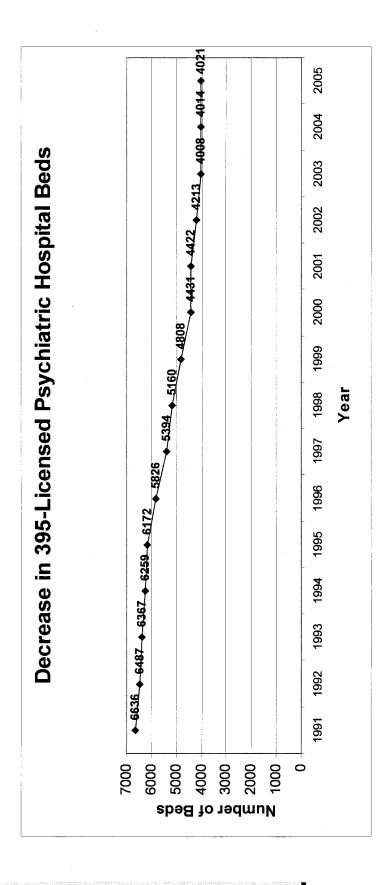
Emergency Department (ED) Use Psychiatric Disorders

- Significant predictors of high ED utilization: prior psychoses, alcohol abuse, and homelessness. number of ED visits, prior number of hospitalizations, and history of depression,
- At a 6.4% prevalence rate, Florida's EDs treat an disorders every day or more than 454,000 estimated 1,245 patients with psychiatric visits/year.
- Homeless individuals account for 30 percent of ED use for psychiatric emergency care; 33% of homeless individuals have one or more ED encounters annually.
- Homeless individuals are more likely than other episodes of service and to be hospitalized after emergency service patients to have multiple the emergency department visit.

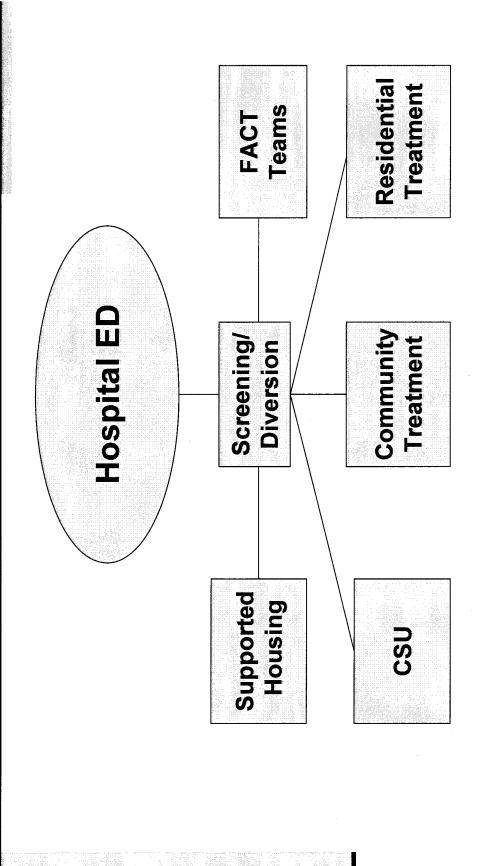
Acute and Emergency Care Issues

- Psychiatric and substance abuse patients disproportionate share of total ED visits. represent the 'frequent flyers' and a
- Increases in ED boarding.
- Reduction in overall psychiatric acute care bed supply and an underfunded publicly financed acute and emergency care system.
- Shortage of CSU and short-term residential beds.
- ED "revolving door" because of lack of postdischarge services.
- Shortage of low-income housing; unstable housing.
- Lack of Medicaid and DCF financed community treatment (crisis and recovery-based services).

Acute and Emergency Care Issues



Acute and Emergency Psychiatric Care A New Cost-Effective Approach to



Crisis Stabilization Units

- individuals with acute psychiatric conditions who Crisis Stabilization Units (CSUs) provide brief psychiatric intervention for low-income are a danger to themselves or others.
- CSU stays average 3 days; 90% of admissions are involuntary and a result of law enforcement intervention.
- involuntarily placed pursuant to Chapter 394, F.S. stabilization persons who are voluntarily or **CSUs may screen, assess, and admit for**
- Clients may be provided 24-hour observation, medication, and other appropriate services.
- client's ability to pay and shall be limited in size to a maximum of 30 beds. CSUs must provide services regardless of the

Crisis Stabilization Units

- Florida has 45 public receiving facilities with 923 DCF-purchased CSU beds (765 adult beds and reimbursable hospital psychiatric beds (306 158 children beds); there are 477 Medicaid adults and 171 children's beds).
- DCF estimates that Florida needs 10 CSU beds per 100,000 population.
- Adult Bed Need: 1,395
- Unmet Need: 324 Beds (1,395-[765+306])
- CSU Rates: \$292 no rate increase since 1999 (Recommended rate: \$358).
- Additional Funding: \$30.6 Million for Beds/\$16.1 Million for Rates (75% State-25% Local).

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Short-Term Residential Treatment Facilities (SRTs)

SRTs provide residential care for up to 90 days for individuals experiencing an acute mental health crisis.

SRT Beds in Florida: 269

SRT Facilities in Florida: 11

No SRTs Located in Districts 1, 2, 4, 8, 9, and 13.

Need: Additional SRTs/SRT Beds

Community Treatment – Unmet Needs

- Prevalence of SPMI Adults: 5.4% (13.9M x .054 753,068 x. 33 (SPMI and Seek Treatment – **Currently Served [130,702]).**
 - Unmet Adult Need: 120,070
- Prevalence of SED Children: 7.9% (4.1M x. .079 x 286 (uninsured) x .36 require public coverage.
- Unmet Child Need: 161,654 (207,205- 45,551 [currently served])
- **\$ Needed: Adults \$136.9M; Children \$97.0M**
- Florida ranks 47th in per capita state spending on mental health care.
- ED use drops by 50+% with community treatment.

Assertive Community Treatment

- Florida has 32 FACT Teams.
- The annual cost of a FACT Team is \$1,254,394; total appropriation is \$40.1 million.
- Each team serves 100 individuals; 60% are Medicaid eligible.
- individuals; average monthly caseload in 9/05 Total FACT Team capacity statewide – 3,200 was 2,844 - 94% of statewide capacity.
- successful in engaging individuals in treatment, increasing housing stability and improving hospitalization down 58-78%; ACT highly ACT Findings: ED use down 32-50%, symptoms.
- Needs: Additional FACTs (Adult, Children, Forensic) and Rate Increases.

Model Programs

- Program/ED Case Management Program/Crisis San Francisco General Hospital Frequent User **Resolution Team**
- **Boston Health Care for the Homeless Project**
- Comprehensive Psychiatric Emergency Programs (Maryland, New York)
- Psychiatric Emergency Response Team/Services (Multiple Sites)
- Orlando Community Receiving Center
- Mobile Crisis Teams (Multiple Sites)
- Crisis Family Care (Multiple Sites)
- Crisis Care Center (San Antonio)
- **Assertive Community Treatment (Multiple Sites)**
 - Jail Diversion Programs (Multiple Sites)

Recommendations

- **Needs in Florida; Determine Effect of Psychiatric** Assess Acute and Emergency Psychiatric Care **Emergency Care on ED Overcrowding**
- Expand CSU Capacity Increase Beds/Increase Rates
- **Expand Short-Term Residential Capacity**
- Expand FACT Teams
- Close the Treatment Gap/Achieve Funding Equity
- Increase Permanent and Supported Housing
- Create Integrated Systems of Care

Crohn's Disease and Ulcerative The Epidemiologic Study on Colitis

HB 869 ER (Section 2)

Florida Department of Health Bureau of Epidemiology



Background

- serious chronic disorders of the gastrointestinal Crohn's disease and ulcerative colitis (IBD) are tract
- Approximately 1.4 million Americans are afflicted
- No previous research conducted on IBD in Florida
- (HB869 ER (Section 2)) requires the Florida "Crohn's and Colitis Disease Research Act" Department of Health to conduct an epidemiologic study on IBD

Partners

马 • AHCA

CCFA*

Blue Cross Blue Shield

Medical providers

* Crohn's and Colitis Foundation of America

Purpose

- Determine:
- Prevalence of IBD in Florida
- Demographic characteristics of IBD patients
- Role of environmental and genetic risk factors

Implementation of the Study

- Literature review
- Consultations from experts
- Advisory Committee
- Epidemiologic study
- Information dissemination

Literature Review

Rate of IBD

-Crohn's disease: 162 per 100,000 to

199 per 100,000

-Ulcerative colitis: 170 per 100,000 to

246 per 100,000

Literature Review

- Characteristics of IBD patient:
- Females > 50%
- -Mean age at diagnosis: 33.4 45 years
- Non-Hispanic Whites had a higher rate
- Factors Associated with IBD
- -Family history
- -Smoking

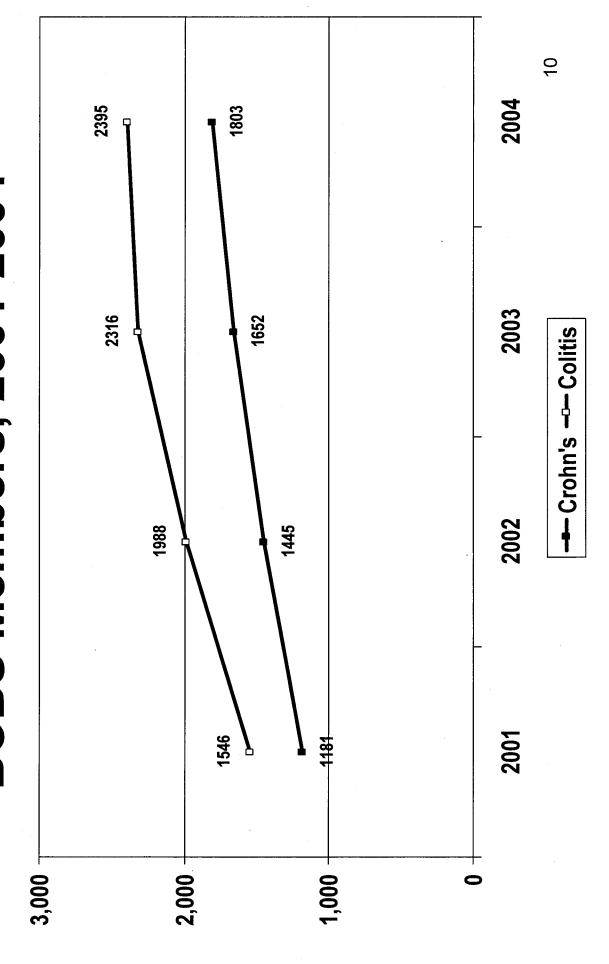
Consultations from Experts

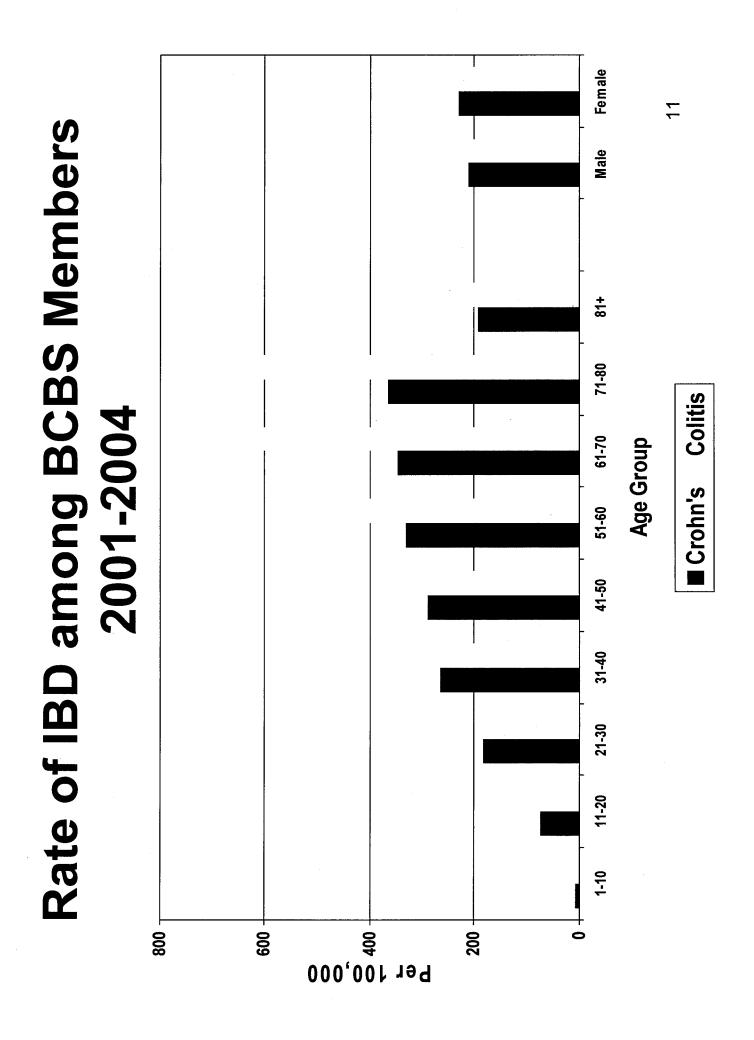
- CDC: Sean Cucchi and Siobhán O'Connor
- **CCFA:** Suzanne Rosenthal, Marjorie Merrick and Florida representatives
 - **University of Miami:** Amy Trachter
- Medical College of Wisconsin: Subra Kugathasan
- Shafran Gastroenterology Center: Ira Shafran
- Kaiser Permanente: Lisa Herrinton
- Crohn's and Colitis support group: David Wolff

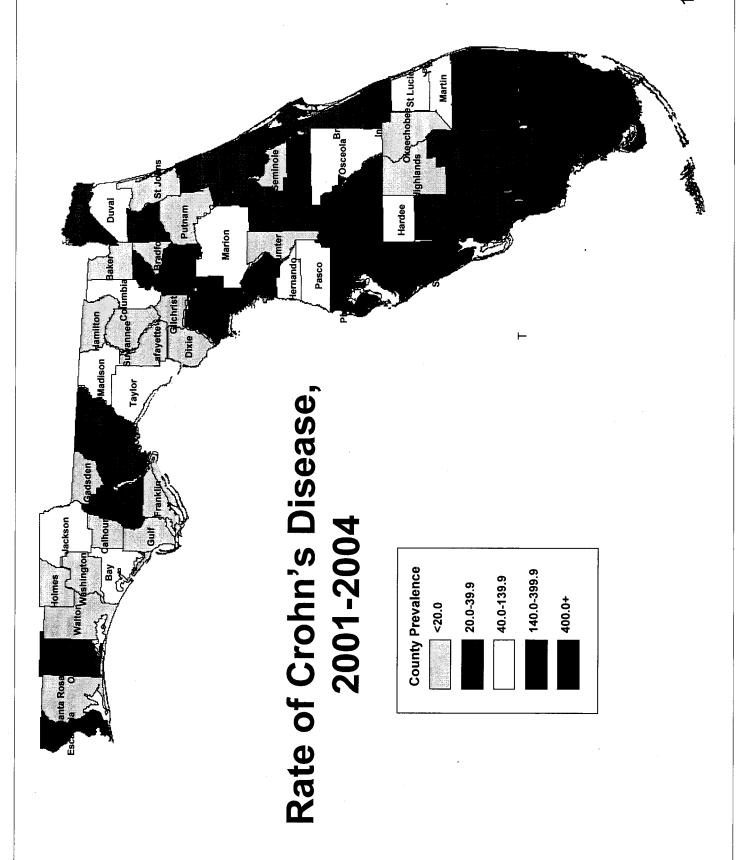
Advisory Committee

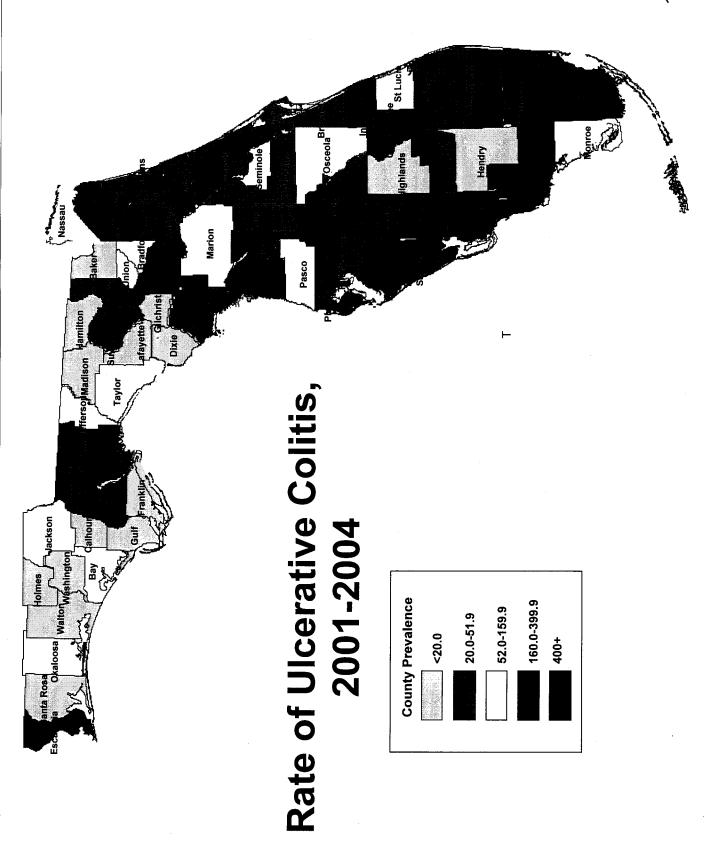
- DOH: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- UF: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine
- AHCA: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- BCBS: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- Florida House Representative: Eleanor Sobel
- Florida Senate: Gwen Margolis
- Physician and Psychologist: Laurence Adams, Amy Trachter
- Fidewater Consulting, Inc.: Frank Mayernick
- **CCFA**: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- CDC: Sean Cucchi and Siobhan O'Connor
- Kaiser Permanente: Lisa Herrinton

Number of New IBD Patients among **BCBS Members, 2001-2004**

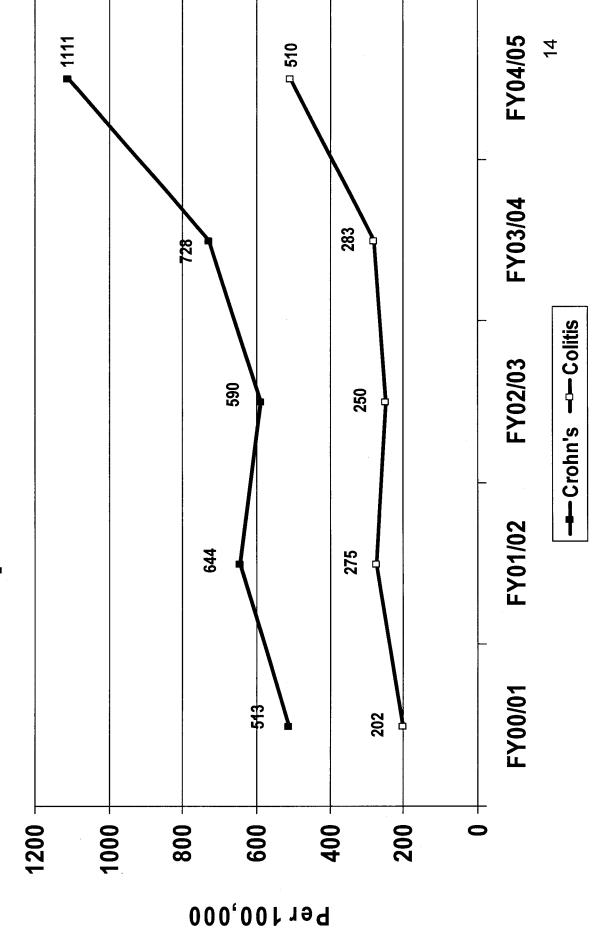




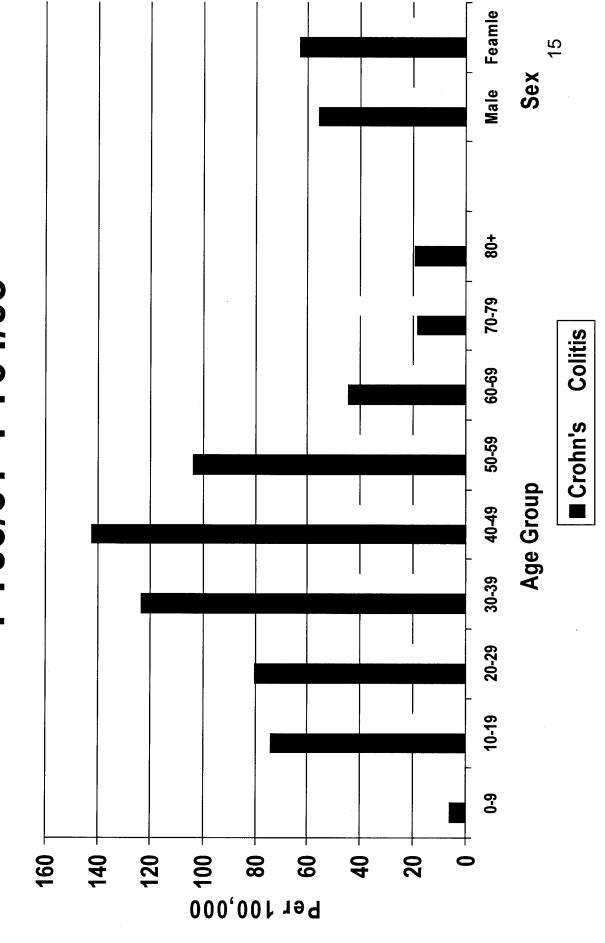




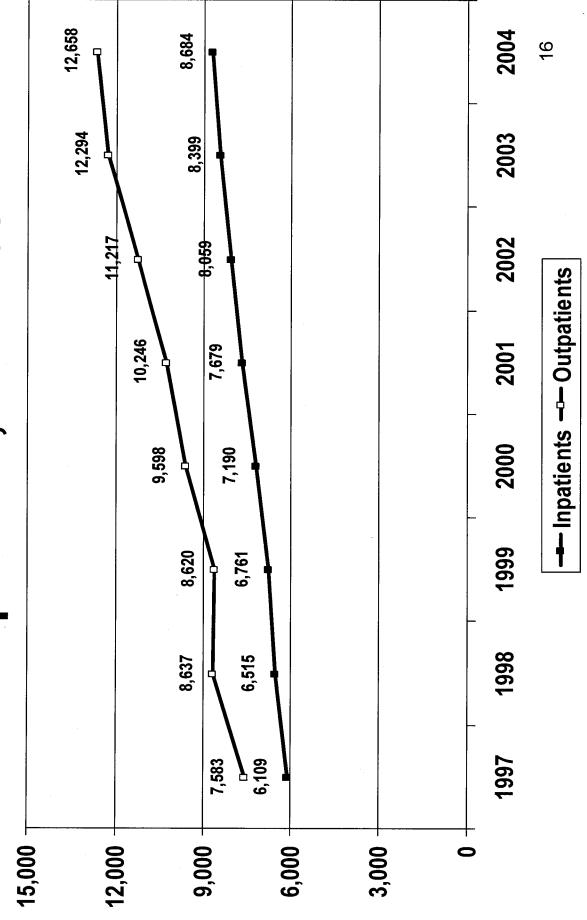
Medicaid Recipients, FY00/01 - FY04/05 Number of New IBD Cases among



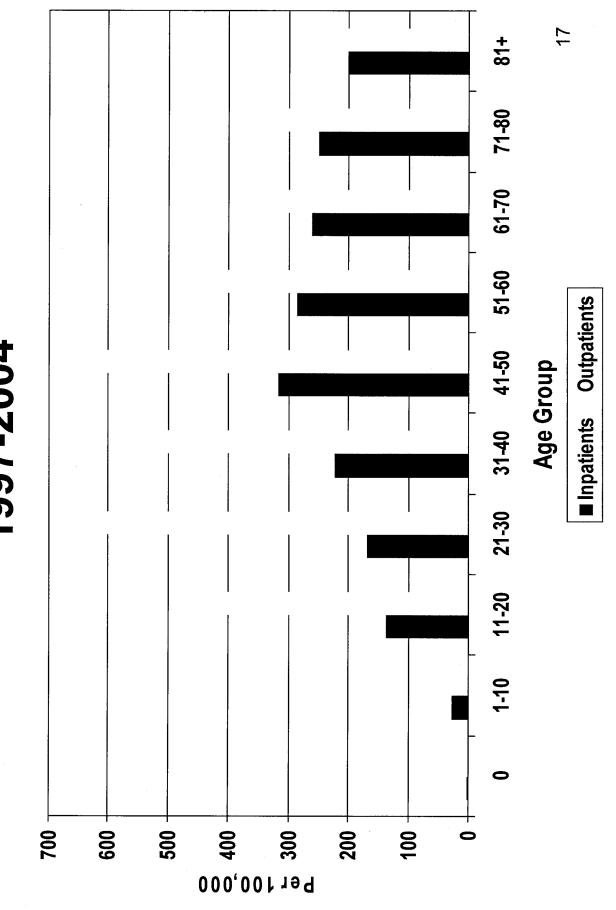
Rate of IBD among Medicaid Recipients, FY00/01- FY04/05

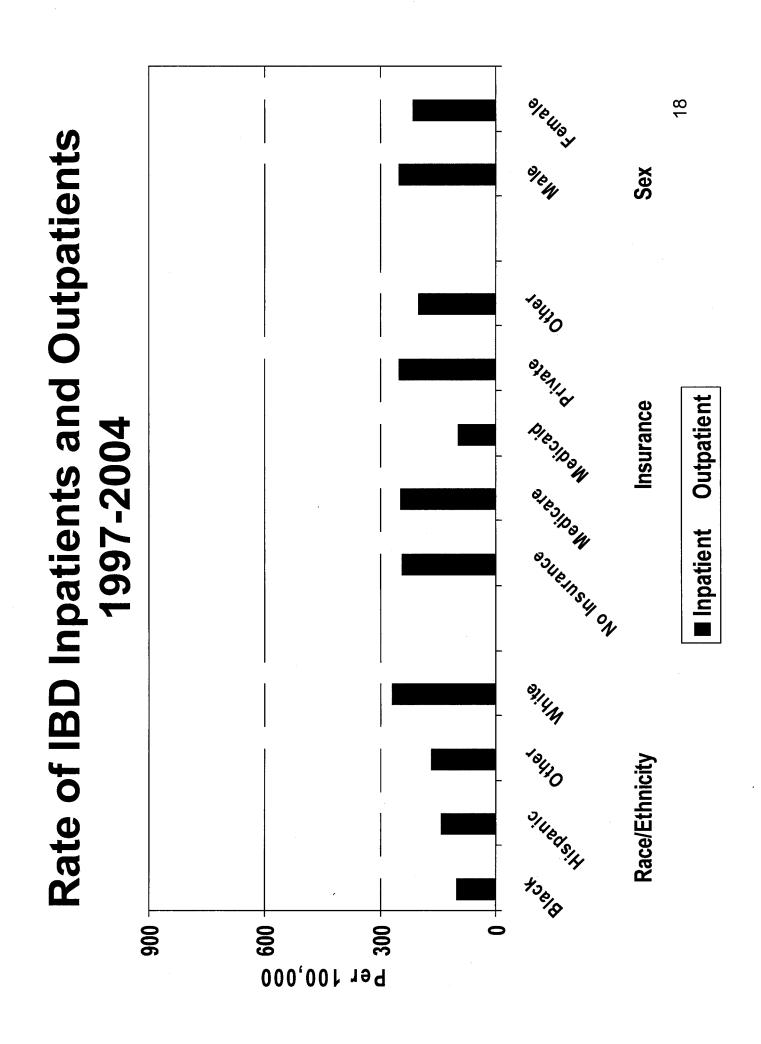


Number of IBD Inpatients and **Outpatients**, 1997-2004



Rate of IBD Inpatients and Outpatients, 1997-2004





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Surveys: BRFSS

- 3.8% of 1,659 survey respondents reported IBD in their household.
- 4.8% of 63 households had more than one patient
- 18.2% patients were hospitalized in the past year.

Surveys: Physicians and Patients

113 physicians

- 14% diagnosed in the past 12 months;
- 40% between age 20 and 45 years
- 93% white and 5% African Americans
- 22% had a family history

27 patients

- Average time with IBD: 11.1 years
- 96% whites, 33% Jewish decent
- 18% with a family history
- 18% rated their health as poor

Conclusions

- Estimated rate: 529 per 100,000
- Crohn's disease: 222 per 100,000 persons
- Ulcerative colitis: 307 per 100,000 persons
- Estimated number of patients: 84,500
- 35,500 with Crohn's disease
- 49,000 with ulcerative colitis

Conclusions

- The rate is higher among:
- Young and middle age adults
- Non-Hispanic Whites
- Residents in Sarasota and Palm Beach counties
- Family history suggests genetic factors associated with IBD
- No environmental factors were identified or confirmed in this study



Final Report of The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Prepared by

Bureau of Epidemiology Florida Department of Health

February 1, 2006

Jeb Bush Governor

M. Rony François, M.D., M.S.P.H., Ph.D. Secretary, Department of Health

EXECUTIVE SUMMARY

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. On June 10, 2005, Governor Jeb Bush signed House Bill 869 entitled "Crohn's and Colitis Disease Research Act" that requires the Florida Department of Health (DOH) to conduct an epidemiologic study on IBD. The goal of this epidemiologic study is to determine: (1) the prevalence of Crohn's disease and ulcerative colitis in Florida; (2) the demographic characteristics of patients with Crohn's disease and ulcerative colitis; and (3) the role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis. The act became effective on July 1, 2005, and the final report is due on February 1, 2006.

An advisory committee was developed for the epidemiologic study. The committee members consisted of representatives and researchers at DOH, the University of Florida, Agency for Health Care Administration (AHCA), Blue Cross Blue Shield (BCBS), Crohn's and Colitis Foundation of America (CCFA), members of the House of Representatives and the Senate, physicians, other medical providers, and other interested groups. Monthly conference calls and an in-person conference were held for the committee members to guide the study.

The study was designed based on an extensive literature review of previous epidemiologic studies and recommendations from national experts. This study received support from the Secretary of the Department of Health, medical providers, and IBD patients throughout the state.

BCBS and AHCA provided large healthcare claim datasets, including BCBS data, Medicaid data, hospital discharge data, and ambulatory patient data. The DOH team conducted gastroenterology physician surveys, an IBD patient survey, and a statewide survey of general population through the Behavioral Risk Factor Surveillance System (BRFSS). The definition of IBD was based on a set of International Classification of Disease Version 9 (ICD-9) codes.

The study collected healthcare claim data with more than 42 million unduplicated records in up to 10 years, and surveyed more than 2,000 households, medical providers, and IBD patients statewide during the study period. The data were analyzed by patient's gender, race/ethnicity, age, residential county, household income, and type of health insurance. Statewide prevalence and number of IBD patients were estimated based on the data of this study and make-up of Florida population.

It is estimated that the prevalence of Crohn's disease is 222 per 100,000 persons and the prevalence of ulcerative colitis is 307 per 100,000 persons in Florida. It is also estimated that there are approximately 35,500 Crohn's disease patients and 49,000 ulcerative colitis patients in Florida. Approximately 11 percent of IBD patients are hospitalized and 12 percent of IBD patients are treated as ambulatory patients every year. The prevalence of IBD was higher among people ages 30 to 80 years old than among other age groups, higher among non-Hispanic Whites than among other race/ethnicity groups, and higher among females than among males. Medicaid recipients had the lowest prevalence rates in either inpatients or ambulatory patients. Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

This study surveyed 27 IBD patients and found a high percent of non-Hispanic Whites, a high percent of patients with a family history, and a high percent of Jewish descents, which may

suggest an association between genetic factors and IBD. The survey examined several environmental factors based on literature reviews, including exposures to cigarette smoking, history of living near cattle and history of tonsillectomy or appendectomy. However, no causal relationship could be established between these risk factors and IBD due to the nature of the small survey of a convenient sample.

Future studies are recommended based on this study. These studies include: (1) a BRFSS survey with increased sample size to better estimate the population-based prevalence of IBD; (2) a case-control study to identify risk factors of IBD; and (3) an IBD patient voluntary registry through their providers. This registry will provide data for a longitudinal follow-up study of IBD patients on treatment, outcome, and quality of life.

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BACKGROUND

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. Approximately 1.4 million Americans are afflicted with these illnesses, 30 percent of whom are diagnosed during childhood. IBD represents a major cause of morbidity from digestive illness, and ulcerative colitis patients are at high risk for developing colorectal cancer. Although IBD is rarely fatal, it is often devastating.

On November 30, 2004, President George W. Bush signed into law the first piece of legislation focused on Crohn's disease and ulcerative colitis, entitled the "Research Review Act." During the 108th Congress, the Crohn's and Colitis Foundation of America and its National IBD Advocacy Network advanced this legislation with three provisions for advancing research on IBD. Provisions were taken directly from legislation, entitled the "Inflammatory Bowel Disease Research Act." Within 12 months after the date of the enactment, the director of the Centers for Disease Control and Prevention was responsible for submitting a comprehensive plan to address the burden of inflammatory bowel disease, in both adult and pediatric populations, to the Senate Health, Education, Labor and Pensions Committee, the House Energy and Commerce Committee, and the House and Senate Appropriations Committee.

There is a perceived increase of IBD in Florida; however, no previous research has been conducted to reveal the prevalence of these illnesses among Florida residents. Therefore, the Florida State Legislature enacted the "Crohn's and Colitis Disease Research Act."

On June 10, 2005, Florida House Bill 869 was approved by Governor Jeb Bush. House Bill 869 is referred to as the "Crohn's and Colitis Disease Research Act." The act requires the Florida Department of Health (DOH) to conduct an epidemiologic study on inflammatory bowel disease in collaboration with the University of Florida College of Public Health and Health Professions, and requires the establishment of an IBD study group that must consist of representatives from the DOH, the Agency for Health Care Administration (AHCA), Crohn's and Colitis Foundation of America (CCFA), the House of Representatives, the Senate, medical providers, and other interested groups. The effective start date is July 1, 2005, and the final report is due to the Governor and the Florida Legislature by February 1, 2006.

PURPOSE OF THE STUDY

The purpose of this study is to work with the University of Florida and other agencies and organizations to conduct an epidemiologic investigation. The goal of this epidemiologic study is to determine the:

- 1. Prevalence of Crohn's disease and ulcerative colitis in Florida.
- 2. Demographic characteristics of patients with Crohn's disease and ulcerative colitis.
- 3. Role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis.

IMPLEMENTATION OF THE STUDY

Literature Review

As the first step of study design, DOH conducted an extensive literature review for studies on IBD. The project coordinator searched the Internet and journals to identify previous epidemiologic studies on both adult and childhood IBD. Through the literature review, DOH gathered information regarding potential and known IBD risk factors, epidemiologic and clinical characteristics of patients with IBD, and potential environmental exposures for IBD.

Drs. Robert Sandler and Edward Loftus (Sartor RB, Sandborn WJ, eds., Kirsner's *Inflammatory Bowel Diseases*, 6th ed., New York: Saunders, 2004) reviewed risk factors for IBD, including demographic characteristics of patients, diet, breast feeding and perinatal events, marital status, occupation and social class, oral contraceptives, cigarette smoking, non steroidal anti-inflammatory drugs, appendectomy, measles, and other miscellaneous factors. Sandler and Loftus conclude that there is undisputable evidence of heritable factors in the genesis of IBD, and environmental influence may attribute to 85-90 percent in ulcerative colitis and 50-55 percent in Crohn's disease. Smoking is highly associated with Crohn's disease, as is nonsmoking with ulcerative colitis. Truelove (Br Med J 1961:1:61) noted cow's milk might exacerbate symptoms of ulcerative colitis.

Dr. Edward Loftus (Gastroenterology, 2004:126:1504-17) states that previous studies have provided insight into the differences in incidence of IBD across age, time, and geographic region, suggesting that environmental factors can significantly modify the expression of these conditions. They suggest the strongest risk factors to be identified at this time are family history of IBD, cigarette smoking, and appendectomy. Research also suggests variation in the demographics of IBD patients:

- Gender: Females tend to have a predominance of Crohn's disease, whereas men tend to have a higher incidence of ulcerative colitis.
- Age: Both Crohn's disease and ulcerative colitis are most commonly diagnosed in late adolescence and early adulthood, however, the diagnosis may occur at any age.
- Race/Ethnicity: Although Whites have a higher incidence of IBD, the incidence among African Americans is approaching that of Whites. Asian Americans, Hispanic Americans, and aboriginal North Americans are less likely to develop IBD, especially Crohn's disease. Ethnic and racial differences may be more related to lifestyle and environmental influences than genetic differences.

Consultations from Experts

In addition to the literature search, DOH sought national and local experts to provide insights for developing Florida's IBD research plan. The project coordinator and the team consulted with many researchers nationwide for research methodology. The information received from these experts helped the Florida researchers refine the methodology of the IBD study. From August through December of 2005, DOH communicated with the following individuals and organizations for their suggestions and advice:

- Mr. Sean Cucchi and Dr. Siobhán O'Connor, Centers for Disease Control and Prevention (CDC), discussed the "Inflammatory Bowel Disease Research Act," which requires the CDC, in conjunction with CCFA, to conduct a national IBD epidemiology study. DOH requested information regarding CDC's research approach and methodology for data collection at the national level.
- Ms. Suzanne Rosenthal, CCFA Co-Founder, and Chairman of the Board Emeritus, and Marjorie Merrick, CCFA Vice President of Research and Scientific Programs provided contact information for national IBD experts, potential funding sources, and guidance in developing methodology.
- Florida CCFA representatives provided contact information for Florida physicians, IBD support group facilitators, and IBD awareness activities.
- Dr. Robert Sandler, Chief, Division of Gastroenterology and Hepatology at the University
 of North Carolina, and member of CCFA's National Scientific Committee, provided
 information on IBD epidemiological literature, former IBD study group activities, survey
 development, and future research development.
- Dr. Amy Trachter, Assistant Professor of Clinical Medicine, Department of Medicine
 Division of Gastroenterology, Miller School of Medicine University of Miami, provided
 revisions to patient survey and disseminated surveys to IBD patients. Dr. Trachter also
 offered additional support for developing grant proposals and future IBD research.
- Dr. Subra Kugathasan, Associate professor, Pediatrics, Medical College of Wisconsin, discussed resources imperative for the development and maintenance of a pediatric IBD registry.
- Dr. Ira Shafran, Shafran Gastroenterology Center, provided the "Inflammatory Bowel Disease Questionnaire Treatment Evaluation Form," a survey administered to patients at the Gastroenterology Center.
- Dr. Lisa Herrinton (Co-PI of IBD study funded by CCFA) of Kaiser Permanente Division of Research, provided information regarding research approach and methodology of two CCFA-funded epidemiological studies. She also shared with DOH the prevalence of IBD among nine health plans across the United States (U.S.), and incidence and prevalence of IBD at Kaiser Permanente, Northern California.
- Mr. David Wolff, Crohn's and Colitis support group facilitator, provided information about IBD patients and the daily implications of living with these illnesses. Mr. Wolff gave insight for the development of a pilot patient survey and assisted in the distribution of surveys to support group members.

Advisory Committee

The study advisory group (a.k.a. Advisory Committee) consisted of epidemiologists at DOH, analysts at AHCA and Blue Cross Blue Shield, physicians and researchers at the University of Florida, members of the House of Representatives and the Senate, representatives from CCFA, medical providers, and other interested groups. The group welcomed any interested organization or individual to participate in the study group.

The first Advisory Committee conference call was held on June 14, 2005. Representatives from the DOH and the University of Florida (UF) participated in the conference call. The group decided to appoint a coordinator, develop an advisory committee, conduct monthly conference calls, and schedule an in-person meeting for advisory members. The group also approved the data collection methodology proposed by the DOH.

Regan Glover of the DOH was appointed as the project coordinator on July 18, 2005.

A letter of invitation to join the Advisory Committee was sent to medical providers, the legislature, representatives from Blue Cross Blue Shield of Florida, state and national Crohn's and Colitis Foundation of America representatives, and the Agency for Health Care Administration. Those interested in joining the committee and/or following the study were placed in a contact database.

Members of the Advisory Committee, consultants, and analysts for this study are:

- AHCA: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- BCBS: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- CDC: Sean Cucchi and Siobhan O'Connor
- CCFA: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- DOH: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- Florida House Representative: Eleanor Sobel
- Florida Senate: Gwen Margolis
- Kaiser Permanente: Lisa Herrinton
- Tidewater Consulting, Inc.: Frank Mayernick
- Physician: Laurence Adams
- Psychologist: Amy Trachter
- UF: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine

Conference calls were held on August 11, September 1, October 6, November 3, 2005, and January 18, 2006. Representatives from a number of agencies, universities, and organizations, as well as interested individuals, participated in the conference calls. The Advisory Committee provided recommendations for the following issues:

- Requirements of House Bill 869.
- Identification of additional members for the study advisory group.
- Plan of study, including overall approach and timeline.
- Diagnoses and procedure codes (ICD-9) for identifying IBD cases in claim data.
- Methods of conducting a survey of GI physicians and IBD patients.
- Development of the pediatric survey and cover letter.
- Survey questions to be added to statewide Behavioral Risk Factor Surveillance System (BRFSS).
- Progress of the study, including data analyses and survey response.
- Preliminary findings of the study.

On November 15, 2005, the Advisory Committee had an in-person meeting in Gainesville, Florida. The participants reviewed preliminary findings and discussed strengths/limitations of study methods and potential sources of data dissemination.

Information Dissemination

The DOH Bureau of Epidemiology made great efforts to disseminate the information regarding the study, including the purpose, methods, and preliminary results to public health professionals, medical providers, Advisory Committee members, and the general public during the entire study period.

- To public health professionals:

- The Bureau published an article introducing the new research in *Epi Update* in July 2005. *Epi Update* is a web-based weekly journal published by the Bureau of Epidemiology. A follow-up article to update the progress of the study was published in *Epi Update* in September 2005.
- The study was introduced to county health departments on a bi-weekly conference call in August 2005.
- An overview of the IBD study was submitted to The Health Advisor, which is the
 forum to spotlight Department of Health special events, people, programs, and
 statistics. The newsletter is sent to county health departments, Department of Health
 units, legislators, and others involved in health around the state and country. The
 article will appear in the January/February 2006 issue.

- To Advisory Committee members:

 Plans, progress of the implementation of the study, and preliminary results were provided to, and reviewed by, the Advisory Committee at monthly conference calls and the in-person meeting in November.

- To Medical providers:

 The study was introduced to gastroenterologists at the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples, Florida, on September 9-11, 2005.

- To interested groups and individuals:

- The project coordinator presented preliminary findings for Crohn's Disease at the CCFA Fourth Annual Advances in IBD Research in Miami Beach, Florida, in December 2005.
- Per suggestion from a spokesperson for the national chapter of CCFA, a letter was sent to former first lady, Barbara Bush, introducing the Florida IBD study and inviting her to attend a meeting where the findings from this study will be presented.
- Frequent conversations were maintained via e-mails and phone calls between the project coordinator and IBD support groups in the state.

METHODS

Sources of Data

When sources of population-based data were identified, the DOH research team found that all databases available were developed for purposes other than IBD epidemiologic study, and not a single database was available that would meet the specific needs for this study. Therefore, the

research team decided to collect a number of large databases that each covers part of the IBD population and then combine the information from these databases for a comprehensive result.

The data included in this study consisted of healthcare claim data (hospital discharge data, ambulatory care data, Blue Cross Blue Shield data, and Medicaid data), and survey data (physician survey, patient survey, and BRFSS survey). Collectively, these data covered a majority of the Florida population and provided a well-represented prevalence of IBD in Florida.

Blue Cross Blue Shield (BCBS) claim data

BCBS of Florida provided claim data for their members from calendar years 2001 to 2005. BCBS is one of the major private health insurance carriers, with approximately 30 percent of Florida's commercial market share. More than 2.5 million BCBS members in Florida receive medical services every year. BCBS members consist of males and females of all ages and races. A majority (more than 80 percent) of members who had a claim record are under the age of 65. Claim data capture information on hospitalizations and clinic visits.

The data were unduplicated to provide the number of patients, instead of the number of medical services. Therefore, if a patient with IBD had more than one visit, he or she was only counted once during the data collection timeframe. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555.9), chronic proctitis (556.2), chronic sigmoiditis (556.3), colitis (556.8, 556.9), enteritis (555.0, 555.1), ileitis (555.2), and other and unspecific colitis (558.9). Data were broken down by patient's age, sex, and residential county.

The DOH included data in four years (2001-2004) in this study, with 10,970,547 person-years. On average, 2,742,637 BCBS members were included in the data each year during 2001-2004.

Medicaid data

Medicaid claim data in fiscal years (FYs) 2000-2004 were provided by AHCA. Medicaid data included all claims, both hospitalizations and clinic visits, for more than one million Medicaid recipients in Florida. Medicaid recipients consist of people of all ages, with more than 50 percent of recipients who are under age 20.

The data were unduplicated to count only the number of patients who received medical care. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555), ulcerative colitis (ICD-9 code: 556), and other IBD (ICD-9 code: 558). Data were broken down by patient's age, sex, and residential county.

Data in all five years (FYs 2000-2004) were included in the study. The data contain 5,922,697 person-years of records, with an average of 1,184,539 recipients each year.

Ambulatory patient data

AHCA provided ambulatory patient data for fiscal years1997-2004. The ambulatory patient data are collected from freestanding ambulatory surgical centers, lithotripsy centers, cardiac catheterization laboratories, and short-term acute care hospitals. Ambulatory patients are those who have a face-to-face encounter with a provider, and who are not formally admitted

as an inpatient in an acute care hospital setting, and not treated in the emergency room. The ambulatory patient data include patients of all ages and races, regardless of the type of a patient's medical insurance.

Disease diagnoses were grouped into several categories based on either primary diagnosis or any of the secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all eight years were included in the analysis. There were 12,710,291 patient records analyzed, with an average of approximately 1.6 million patients every year. Patients might have more than one ambulatory visit either in a single year or in different years. The DOH unduplicated multiple visits in two ways: 1) to count each patient only once for the entire 8-year period for number of "new" IBD patients among ambulatory patients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among ambulatory patients. Data were analyzed by race, age, residential county, and type of medical insurance.

Hospital discharge data

AHCA also provided hospital discharge data for 1995-2004. The hospital discharge data include all inpatients of all ages and types of medical insurance.

Disease diagnoses were grouped into several categories based on either primary or secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all 10 years were included in the analysis. There were 12,769,086 inpatient records analyzed, with an average of approximately 1.2 million patients every year. Many patients had more than one hospitalization either in a single year or in different years. The DOH unduplicated multiple hospitalizations in two ways: 1) to count each patient once in the entire 10-year period for number of "new" IBD patients among inpatients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among inpatients.

IBD inpatients who had ambulatory visit(s) were excluded from the analyses to avoid duplication for patients receiving medical care in hospitals. Data were analyzed by race, age, residential county, and type of medical insurance.

Gastroenterology (GI) Physician survey

DOH Bureau of Epidemiology developed a gastroenterology (GI) physician survey in August 2005. (See attachment 1 for the survey questionnaire.) The survey was designed to estimate:

- Patient demographics
- Number of newly diagnosed IBD cases within past 12 months
- Severity of illness measured by hospitalizations due to IBD
- Role of family history
- Patient's enrollment for colon cancer surveillance

The survey questionnaire was sent to 660 gastroenterologists in Florida by mail. The DOH research team received 132 returned survey questionnaires, among which 113 were completed.

Regan Glover, the project coordinator, distributed the survey questionnaires at the general sessions of the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples Florida on September 9-11, 2005. Ten completed surveys were received from the conference attendees.

Pediatric GI physician survey

The Bureau of Epidemiology revised the GI-physician survey questionnaire to address pediatric IBD patients seen by pediatric specialists. Data collected were similar to that collected from the GI physician survey. Survey questionnaires were distributed to 41 Florida members of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) via mail. A cover letter and pre-paid return envelope were included with the mailed survey. Collection period began September 26, 2005, and ended on October 26, 2005. Eight (20 percent) of 41 physicians returned completed survey questionnaires.

IBD patient survey

The DOH team developed a short anonymous survey of IBD patients. (See attachment 2 for the questionnaire.) Dr. Amy Trachter and GI physicians assisted with the design of questionnaire. The purpose of this survey was to obtain information on risk factors of IBD, particularly environmental factors and genetic factors.

The survey was implemented from December 23, 2005, to January 10, 2006. To keep responses anonymous, the DOH did not disseminate directly surveys to IBD patients. Instead, the survey questionnaire was emailed to facilitators of eight CCFA support groups. The facilitators were asked to distribute the survey questionnaire to their group members though e-mails. The total number of IBD patients who received the questionnaire from their support group facilitator was unknown. IBD patients who were willing to participate in the survey completed survey and returned surveys to DOH either electronically (e-mail/fax), or by U.S. Postal Service. The DOH received 27 completed survey questionnaires from IBD patients with two support groups in Miami and Sarasota.

Behavioral Risk Factor Surveillance System survey

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a statewide random telephone survey of civilian, non-institutionalized adults (age 18 and older). The BRFSS is an ongoing collaborative survey with the CDC to monitor trends in risk behaviors related to preventable chronic diseases and conditions in Florida. Respondents are asked about health status, health behaviors, use of screening services, and access to health insurance and health care.

Three questions were designed by the Bureau of Epidemiology to survey the general population. These questions are:

- (Q1) Has anyone, including yourself, in your household, ever been told by a doctor or other health professional that you have Crohn's disease or ulcerative colitis?

- (Q2) How many people in your household have been told that they have Crohn's disease or ulcerative colitis?
- (Q3) How many of these people have been admitted to a hospital in the past 12 months because of Crohn's disease or ulcerative colitis?

The purpose of these questions is to assess the prevalence of IBD (Q1), familial aggregation of IBD cases (Q2), and severity of IBD (Q3) among general population. These questions were included in the BRFSS survey from September 1, 2005, through December 15, 2005. There were 1,847 individuals surveyed, among whom 1,678 responded to these three questions.

Medicare data were requested in October 2005; however, approval to use those records was not received as of the date of this report.

Definition of IBD

The following are the International Classification of Disease Version 9 (ICD-9) codes that were used to define Crohn's disease, ulcerative colitis, and other IBD in healthcare claim data:

Crohn's disease:

555.0: Ileitis (regional, segmental) and Regional enteritis or Crohn's disease of duodenum, ileum, or jejunum

555.1: Colitis (granulmatous, regional, or transmural) and regional enteritis or Crohn's disease of colon, large bowel, or rectum

555.2: Ileitis

555.9: Crohn's disease NOS

Ulcerative Colitis:

556.0: Ulcerative (chronic) enterocolitis

556.1: Ulcerative (chronic) ilecocolitis

556.2: Ulcerative (chronic) proctitis

556.3: Ulcerative (chronic) proctosigmoiditis

556.5: Left-sided ulcerative (chronic) colitis

556.6: Universal ulcerative (chronic) colitis

556.8: Other ulcerative colitis

556.9: Ulcerative colitis, unspecified.

Other IBD:

558.9: Other and unspecified (noninfectious gastroenteritis and colitis)

Procedure code:

45.23: Colonoscopy

Analysis

The primary purpose of analysis was to identify prevalence of IBD, patients' characteristics, and IBD related risk factors. The DOH team did not attempt to make comparisons of prevalence among subpopulations. Therefore, the team did not conduct any statistical tests for difference

in prevalence among subpopulations, nor to adjust prevalence by age-distribution of the population. The methods that the DOH used for this study were:

1. Claim data

- a. Numbers of patients with IBD were tabulated.
- b. Prevalence of IBD was estimated in various populations. Prevalence is the proportion of the population with IBD in a specific year. The prevalence was calculated as follows:
 - i. BCBS data and Medicaid data: by sex and age
 - ii. Hospital discharge data and ambulatory patient data: by sex, age, race, and ethnicity, and type of insurance
- c. Incidence of IBD was estimated for BCBS IBD patients. Incidence is the number of new cases diagnosed per 100,000 persons in a year. Although BCBS data counted only new patients to the BCBS system in the four-year period, some of "new" patients might have been diagnosed before the study period.
- d. Proportion of IBD patients with a colonoscopy was calculated.

2. BRFSS survey data

Prevalence of IBD was estimated by race and household income. The prevalence was not weighted by the probability of respondents being selected for the survey because the weight variable was not available during preparation of this report. Responses of "don't know" or "unsure" were excluded from analyses.

3. Physician survey

Percents of responses were tabulated for estimates of:

- a. Newly diagnosed cases (within past 12 months)
- b. Patient demographics
- c. Severity of illness (hospitalizations)
- d. Role of family history
- e. Colon cancer surveillance

4. Patient survey

Percents of responses were tabulated for estimates of:

- a. Patient demographics (sex, race/ethnicity and region)
- b. Age of diagnosis/time lived with IBD
- c. Type of IBD (Crohn's disease and ulcerative colitis)
- d. Severity of symptoms (mild, moderate, severe)
- e. Presence of family history
- f. Risk behaviors (active or passive inhalation of cigarette smoke)
- g. General assessment of health

There was a close collaboration among BCBS, AHCA, and DOH representatives and data analysts for this study. John Montgomery, John Williams, and John Bookstaver provided information on BCBS and conducted analyses of BCBS claim data. AHCA representatives Mel Chang, Beth Eastman, Susan Chen, Gloria Barker, Adrienne Henderson, and Cliff Schmidt provided support and conducted analyses on Medicaid data, hospital discharge data, and ambulatory patient data. DOH epidemiologist Youjie Huang and health data analyst Curt Miller analyzed the survey data and conducted part of the analyses of hospital discharge data and ambulatory patient data.

RESULTS

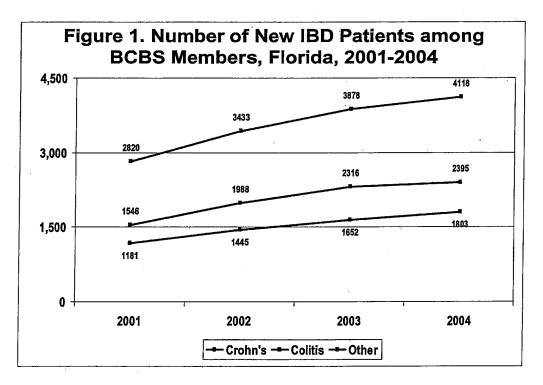
BCBS data

During 2001-2004, 6,373 BCBS members were diagnosed with Crohn's disease and 8,658 were diagnosed with ulcerative colitis. In the BCBS claim data, an average of 2,742,637 BCBS members per year received medical services. Among those members, 1,520 members, on average, were diagnosed with Crohn's disease and 2,061 were diagnosed with ulcerative colitis per year. (Table 1)

Table 1. Average Number of BCBS Members with IBD per Year, Florida, 2001-2004

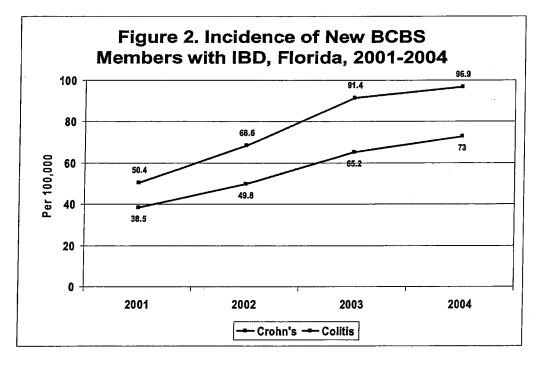
	All IBD	Crohn's	Colitis	Other	# of Members	
Total	7,144	1,520	2,061	3,563	2,742,637	
By Age Group					,	
1-10	25	7	9	10	289,104	
11-20	196	81	48	68	431,765	
21-30	472	150	- 131	180	350,594	
31-40	841	234	258	349	352,003	
41-50	1,231	287	381	563	398,637	
51-60	1,464	305	420	738	370,815	
61-70	1,294	222	388	684	256,748	
71-80	1,144	156	311	677	170,573	
81+	430	59	102	269	122,395	
By Sex	•					
Male	3,006	684	956	1,365	1,296,831	
Female	4,091	826	1,092	2,173	1,445,806	

Number of members who were first time diagnosed with Crohn's disease increased by 55 percent from 1,546 in 2001, to 2,395 in 2004. Similarly, the number of members diagnosed with ulcerative colitis increased by 53 percent from 1,181 in 2001, to 1,803 in 2004, and the number of patients diagnosed with other colitis increased by 45 percent from 2,820 in 2001, to 4,118 in 2004 (Figure 1).



The overall four-year prevalence was 222 per 100,000 persons for Crohn's disease, 301 per 100,000 persons for ulcerative colitis, and 520 per 100,000 persons for other IBD.

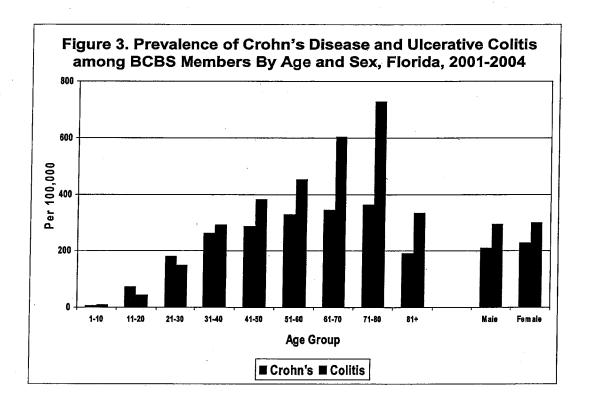
The incidence (number of new patients among 100,000 people at risk in a year) increased during the four-year period. For Crohn's disease, the rate increased by 92 percent from 50.4 per 100,000 to 96.9 per 100,000 person. The prevalence of ulcerative colitis increased by 90 percent. (Figure 2)



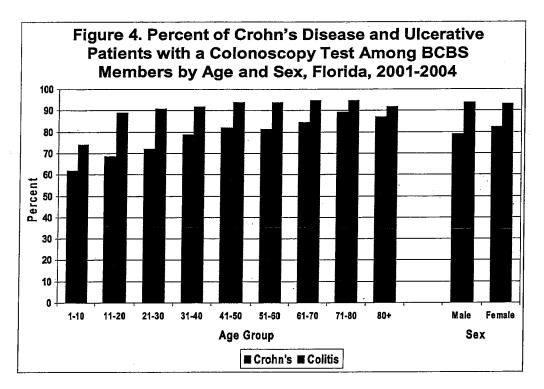
During the four-year period, the number of patients diagnosed with Crohn's disease and ulcerative colitis increased by age, and reached a peak in the 51-to-60-year-old age group (Table 1).

The four-year prevalence was the highest among people between the ages of 71 and 80 years. The prevalence increased by age, except among people age 81 years and older. (Figure 3)

The prevalence was slightly higher among females than among males for Crohn's disease (229 per 100,000 people versus 211 per 100,000 people), and ulcerative colitis (302 per 100,000 people versus 295 per 100,000 people). (Figure 3)

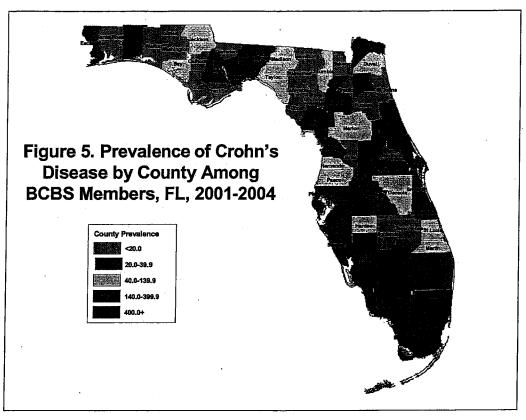


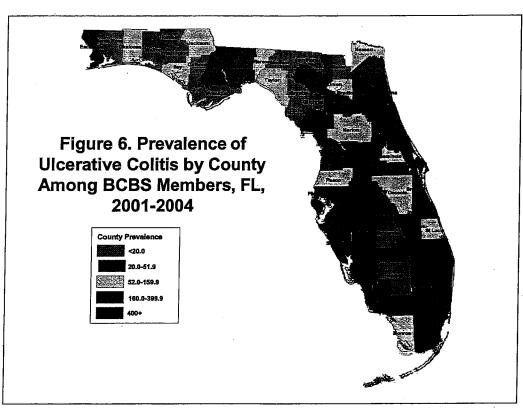
A colonoscopy is a medical procedure that is required to confirm the diagnosis of Crohn's disease and ulcerative colitis. Among BCBS members, a majority of new patients with Crohn's disease and ulcerative colitis had a colonoscopy. The percent of Crohn's disease patients who had a colonoscopy increased by age, from 61 percent among patients under age 11, to 87 percent among patients aged 80 years and older. The percent of patients with a colonoscopy was higher among ulcerative colitis patients than among Crohn's disease patients. Ninety percent of patients with ulcerative colitis had a colonoscopy with the exception of patients under age 11. (Figure 4)



Among Crohn's disease patients, more females (82 percent) had a colonoscopy than did males (79 percent). Among ulcerative colitis patients, 93 percent of both males and females had a colonoscopy.

Among BCBS members, the prevalence of Crohn's disease was greater than 400 per 100,000 in Liberty, Wakulla, Jefferson, Brevard, Glades, and Lee counties. (Figure 5) Liberty, Wakulla, Leon, Columbia, Brevard, Glades, Orange, Hillsborough, Polk, Sarasota, Palm Beach, and Broward counties had a prevalence of ulcerative colitis greater than 400 per 100,000 people. (Figure 6) Liberty, Wakulla, Brevard, and Glades counties had a high prevalence for both Crohn's disease and ulcerative colitis.





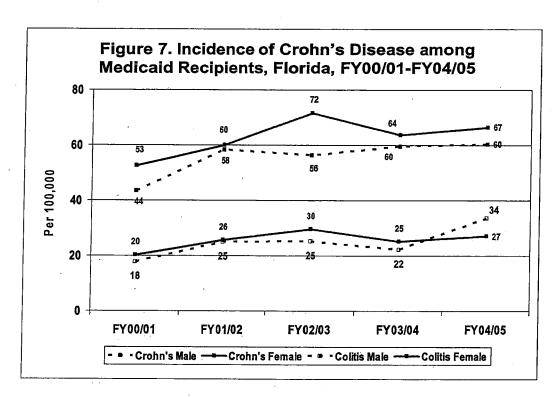
Medicaid data

The number of Medicaid recipients receiving medical service varied greatly during FY 2000-2001 through FY 2004-2005. The average number of recipients with at least one claim for medical service was 1,184,535 per year. The average number of Medicaid recipients diagnosed with Crohn's disease per year was 717 patients, with a prevalence of 61 per 100,000 people. On average, 304 recipients per year were diagnosed with ulcerative colitis, with a prevalence of 26 per 100,000 people. The number of recipients diagnosed with other colitis was 26,055 per year with a prevalence of 2,200 per 100,000 people. (Table 2)

Tables 2. Number of Patients with IBD among Medicaid Recipients, Florida, FY00/01-FY04/05

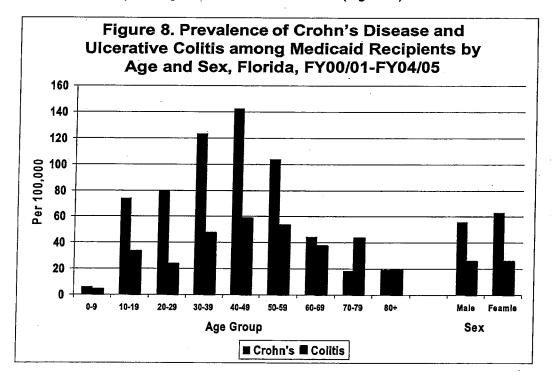
		· · · · · · · · · · · · · · · · · · ·			
FY00/01	FY01/2	FY02/3	FY03/4	FY04/5	
1,042,369	1,084,413	895,044	1,170,599	1,730,249	
	Crohn's Dise	ase	,		
513	644	590	728	1,111	
348	416	406	474	733	
165	228	184	254	378	
	Ulcerative Co	litis			
202	275	250	283	510	
134	177	168	188	300	
68	98	82	95	210	
	Other				
al 25,966		18,755	27,360	37,411	
13,863	10,990	9,928	14,317	20,076	
12,101	9,793	8,824	13,038	17,333	
	1,042,369 513 348 165 202 134 68 25,966 13,863	1,042,369 1,084,413 Crohn's Dise 513 644 348 416 165 228 Ulcerative Co 202 275 134 177 68 98 Other 25,966 20,785 13,863 10,990	1,042,369 1,084,413 895,044 Crohn's Disease 513 644 590 348 416 406 165 228 184 Ulcerative Colitis 202 275 250 134 177 168 68 98 82 Other 25,966 20,785 18,755 13,863 10,990 9,928	1,042,369 1,084,413 895,044 1,170,599 Crohn's Disease 513 644 590 728 348 416 406 474 165 228 184 254 Ulcerative Colitis 202 275 250 283 134 177 168 188 68 98 82 95 Other 25,966 20,785 18,755 27,360 13,863 10,990 9,928 14,317	

The prevalence of both Crohn's disease and ulcerative colitis increased during FY2000-2001 through FY2004-2005. The prevalence of Crohn's disease increased by 30 percent (38 percent for males and 27 percent for females), and the prevalence of ulcerative colitis increased by 52 percent (87 for males and 35 percent for females). (Figure 7)



The age-specific prevalence was the highest among people between ages 40 and 49 for both Crohn's disease (142 per 100,000 persons) and ulcerative colitis (58 per 100,000 persons).

Females had a higher prevalence of Crohn's disease (63 per 100,000 persons) than males (56 per 100,000 persons). However, the prevalence of ulcerative colitis was the same (26 per 100,000 persons) among both males and females. (Figure 8)



Hospital discharge data

There were 12,769,086 patients discharged from hospitals during 1995-2004. During this period, 187,700 patients were diagnosed with IBD, among whom 15,340 had Crohn's disease and 13,820 had ulcerative colitis.

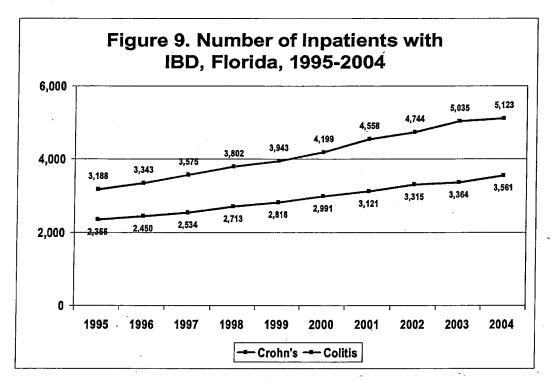
Among patients with Crohn's disease and ulcerative colitis, there were more female patients, than there were male patients. Although most Crohn's disease and ulcerative colitis patients were Whites, many patients of other races/ethnicities were diagnosed with IBD as well. (Table 3)

Table 3. Average Number of New Patients Hospitalized with IBD per Year, Florida, 1995-2004

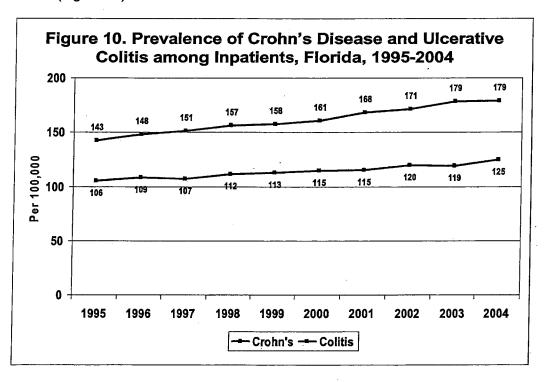
	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	18770	1534	1382	16314					
By Age					By Race				
0-	246	0	0.	246	Black	2,186	92	90	2,039
1-10	1,129	5	3	1,123	Hispanic	2,424	90	117	2,256
11-20	534	60	30	456	Other	442	35	34	383
21-30	1,193	158	83	987	White	13,718	1,318	1,140	11,635
31-40	1,946	227	141	1,638	By Insurance				
41-50	2,207	237	152	1,882	No insurance	1,265	141	72	1,083
51-60	2,156	217	177	1,821	Medicare	8,899	602	741	7,788
61-70	2,708	231	232	2,309	Medicaid	2,120	95	71	1,993
71-80	3,673	260	331	3,172	Private	6,052	646	463	5,090
81+	2,980	139	231	2,681	Other	433	50	35	361
By Sex									
Male	7,134	662	600	6,049					
Female	116,356	872	782	10,265					

New patients, excluding patients who were diagnosed as outpatients

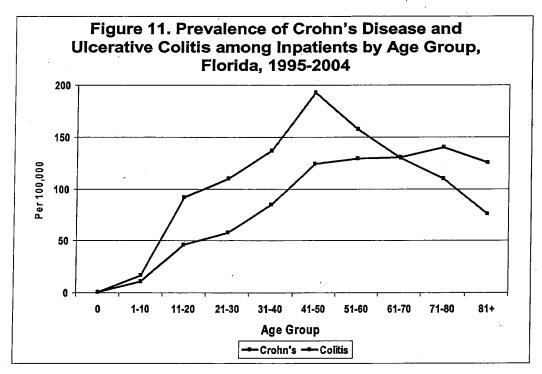
The number of patients with Crohn's disease and ulcerative colitis that were hospitalized increased by 61 percent and 51 percent, respectively, from 1995 to 2004. In 2004, 5,123 Crohn's disease and 3,561 ulcerative colitis patients were hospitalized. (Figure 9) The 10-year overall prevalence was 120.1 per 100,000 people for Crohn's disease and 108.2 per 100,000 people for ulcerative colitis during the 10-year period. For calculating overall prevalence, a patient with an IBD diagnosis was counted once, regardless of how many times the patient was hospitalized in the 10-year period. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with either Crohn's disease and/or ulcerative colitis was 221.0 per 100,000 people among inpatients.



The annual prevalence of Crohn's disease increased by 26 percent, from 143 per 100,000 people in 1995 to 179 per 100,000 people in 2004. The annual prevalence of ulcerative colitis increased by 18 percent, from 106 per 100,000 persons in 1995 to 125 per 100,000 persons in 2004. (Figure 10)



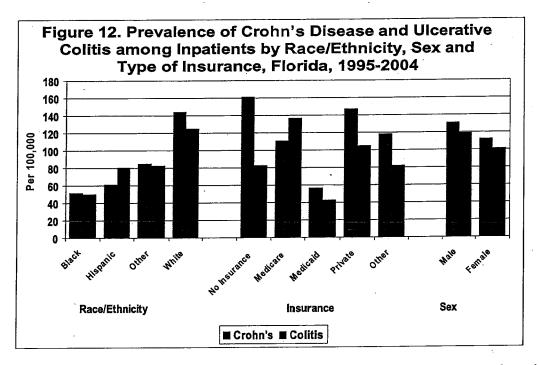
The age-specific prevalence of Crohn's disease increased by age, reached a peak of 193 per 100,000 people among the 41-to-50-year age group, then it decreased to 76 per 100,000 people among people aged 81 years and older. The prevalence of ulcerative colitis also increased by age, reached a peak of 140 per 100,000 people among 41-to-50 year age group, and decreased to 125 per 100,000 people among people aged 81 years and older. (Figure 11)



Whites had the highest prevalence of Crohn's disease (145 per 100,000 people) and ulcerative colitis (125 per 100,000 people) among four race/ethnicity groups. Blacks had the lowest prevalence for both Crohn's disease (61 per 100,000 people) and ulcerative colitis (51 per 100,000 people).

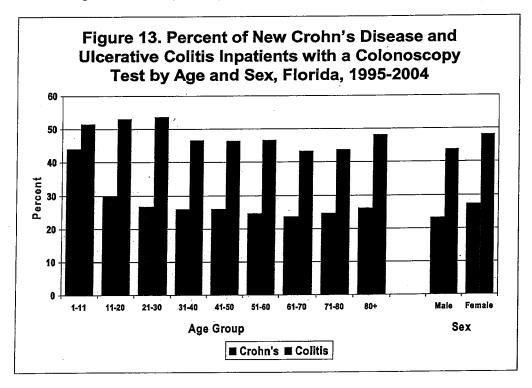
Patients who had a private medical insurance (147 per 100,000 people) and patients without any insurance (162 per 100,000 people) had a higher prevalence for Crohn's disease than their counterparts did. Medicare beneficiaries had the highest prevalence (137 per 100,000 people) of ulcerative colitis. Medicaid recipients had the lowest prevalence of both Crohn's disease (57 per 100,000 people) and ulcerative colitis (43 per 100,000 people).

Males had a higher prevalence of both Crohn's disease (131 per 100,000 people versus 113 per 100,000 people) and ulcerative colitis (119 per 100,000 people versus 101 per 100,000 people) than females. (Figure 12)

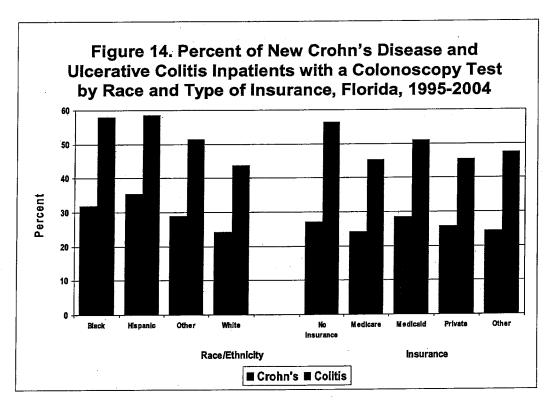


Approximately one quarter (25.5 percent) of new Crohn's disease patients had a colonoscopy. The percent of patients with a colonoscopy was higher among younger patients (under age 20) than among older patients, and higher among females than among males.

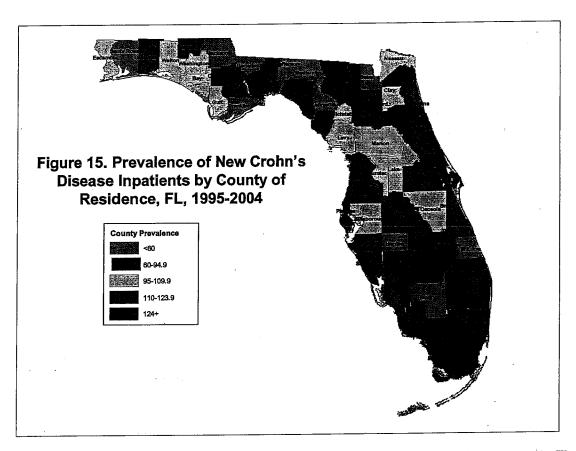
Among new patients with ulcerative colitis, 42.3 percent had a colonoscopy. The percent of patients with a colonoscopy was also higher among patients under age 30 and among females than among their counterparts. (Figure 13)



The percent of new Crohn's disease patients with a colonoscopy was the highest among Hispanics. Both Medicaid recipients and patients without any medical insurance had a higher percent than their counterparts did. The percent of new ulcerative colitis patients with a colonoscopy was higher among Hispanics and Blacks than Whites and people of other races. The percent of ulcerative colitis patients with a colonoscopy was also higher among people without medical insurance and Medicaid recipients than for people with a private insurance and Medicare beneficiaries. (Figure 14)

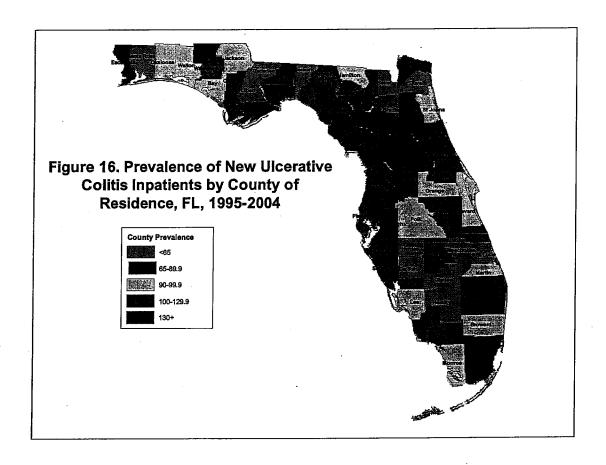


Twelve counties had a 10-year overall prevalence of Crohn's disease of 124 per 100,000 people or greater in Florida. These counties are Holmes, Union, Seminole, Hernando, Pasco, Pinellas, Indian River, Okeechobee, Sarasota, Charlotte, Collier, and Monroe. (Figure 15)



Twelve counties had a prevalence of ulcerative colitis of 130 per 100,000 or greater in Florida. These counties are Gulf, Suwannee, Columbia, Union, Citrus, Sumter, Lake, Hernando, Osceola, Sarasota, Charlotte, and Collier. (Figure 16)

Union, Hernando, Sarasota, Charlotte, and Collier had higher prevalence rates for both Crohn's disease and ulcerative colitis than other counties in Florida during 1995-2004.



Ambulatory patient data

There were 12,710,291 patients who received at least one ambulatory care service during 1997-2004. Among these patients, 22,005 were diagnosed with Crohn's disease, 32,541 were diagnosed with ulcerative colitis, and 120,138 were diagnosed with other colitis.

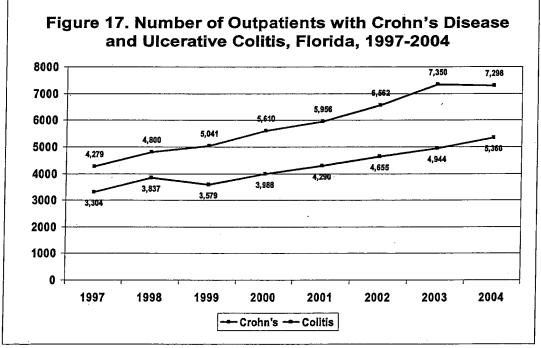
There were more females than males among patients with Crohn's disease and ulcerative colitis. Approximately 80 percent of Crohn's disease and ulcerative colitis patients were White, and 60 percent of patients had a private health insurance. (Table 4)

Table 4. Average Number of New Outpatients with IBD per Year, Florida, 1997-2004

	All IBD	Crohn's	Colitis	Other	1	All IBD	Crohn's	Colitis	Other
Total	20,143	2,751	4,068	15,017					
By Age					By Race				
0-	28	1	3	27	Black	950	111	186	729
1-10	123	11	11	105	Hispanic	1,492	142	268	1,196
11-20	503	135	. 115	314	Other	1,583	292	382	1,007
21-30	1,323	300	327	837	Whites	16,117	2,207	3,232	12,085
31-40	2,374	439	595	1,588	By Insurance				
41-50	3,185	498	707	2,284	No insurance	509	77	100	366
51-60	3,697	494	706	2,803	Medicare	7,337	756	1,291	5,815
61-70	3,836	423	710	2,992	Medicaid	629	91	88	490
71-80	3,768	348	679	3,004	Private	11,100	1,726	2,446	7982
81+	1,306	105	218	1,064	Other	568	101	142	363
By Sex						-			
Male	8,151	1,180	1,915	5,829					
Female	11,993	1,571	2,153	9,189					····

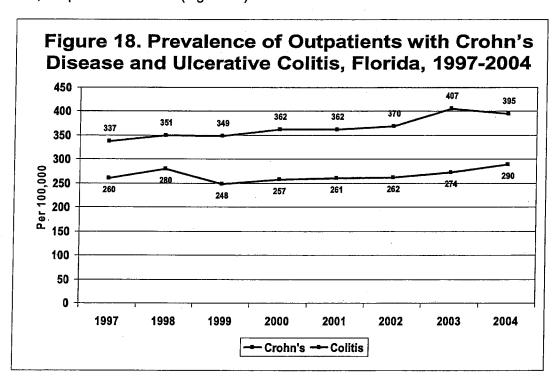
New patients, including patients who were also hospitalized

The number of Crohn's disease patients that were treated as ambulatory patients was 3,304 in 1997 and increased by 62 percent to 5,360 in 2004. The number of ulcerative colitis patients increased by 71 percent, from 4,279 in 1997 to 7,298 in 2004. (Figure 17)



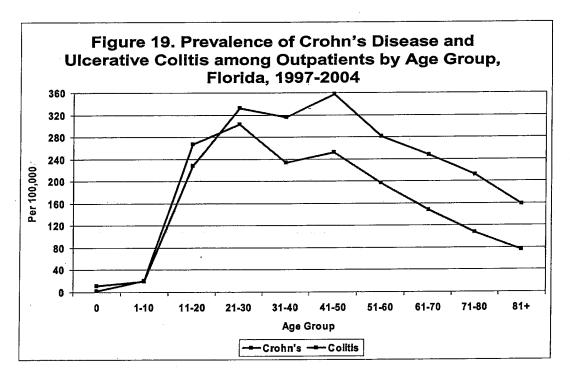
The 8-year overall prevalence (each patient was counted only once) was 173.1 per 100,000 people for Crohn's disease and 256 per 100,000 people for ulcerative colitis during 1997-2004. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with Crohn's disease and/or ulcerative colitis was 412.4 per 100,000 people.

The annual prevalence of ambulatory patients increased for both Crohn's disease and ulcerative colitis in the 8-year period. The prevalence of Crohn's disease increased by 11 percent, from 260 per 100,000 persons in 1997 to 289 per 100,000 persons in 2004. The prevalence of ulcerative colitis increased by 17 percent, from 337 per 100,000 persons in 1997 to 395 per 100,000 persons in 2004. (Figure 18)

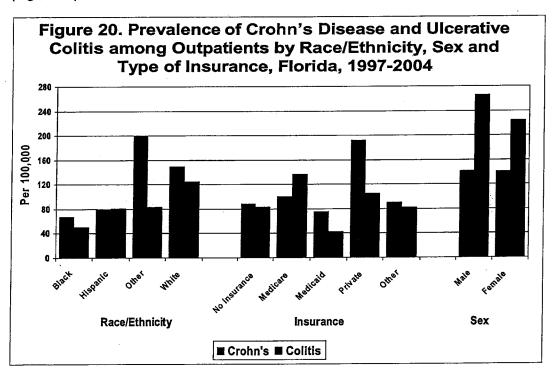


The age-specific prevalence of Crohn's disease increased dramatically in teenagers and peaked in the 21- to 30-year-old age group. Age-specific prevalence decreased among patients aged 30 years and older, with an exception of an increase in the 41- to 50-year-old age group.

The age-specific prevalence of ulcerative colitis increased among patients between ages 11 and 30 years, and then reached a peak of 358 per 100,000 persons among the 41- to 50-year-old age group. The prevalence then decreased by age among people aged 50 years and older. (Figure 19)



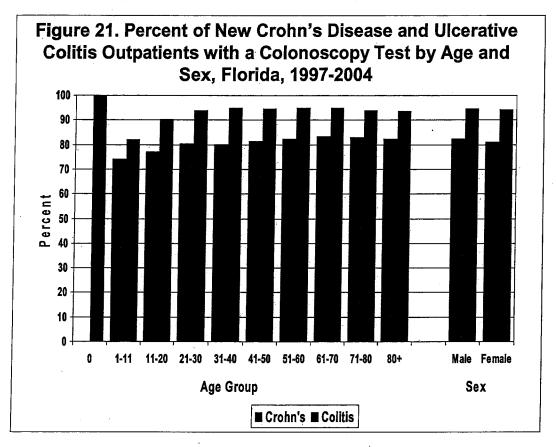
Patients of other races had the highest prevalence of Crohn's disease at 200 per 100,000 people. The prevalence of Crohn's disease among Whites was the second highest at 150 per 100,000 people. The prevalence of Crohn's disease was the highest among patients with a private health insurance (193 per 100,000 people). The prevalence was the lowest among Medicaid recipients (75 per 100,000 people). The prevalence of Crohn's disease was slightly higher among males (143 per 100,000 people) than among females (141 per 100,000 people). (Figure 20)



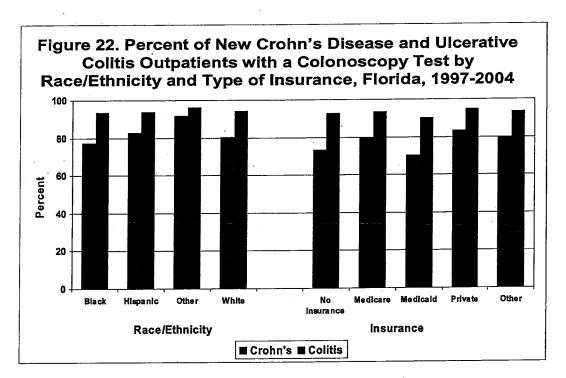
The prevalence of ulcerative colitis was the highest among Whites (125 per 100,000 people), and among Medicare beneficiaries (137 per 100,000 people). The prevalence was the lowest among Medicaid recipients (43 per 100,000 people). Males had a higher prevalence of ulcerative colitis (265 per 100,000 people) than females (224 per 100,000 people). (Figure 22)

Approximately 82 percent of Crohn's disease patients had a colonoscopy. The percent of Crohn's disease patients with a colonoscopy was lower among patients under age 20 than among older patients. The percent was the same among both males and females.

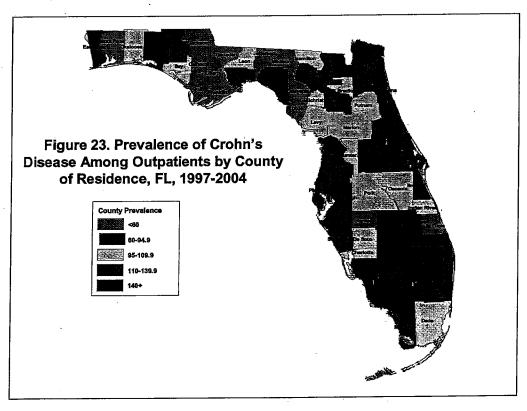
A majority (94 percent) of ulcerative colitis patients had a colonoscopy. The percent of ulcerative colitis patients with a colonoscopy was higher among patients aged 20 years and older. There was no difference in the percentage between males and females. (Figure 21)



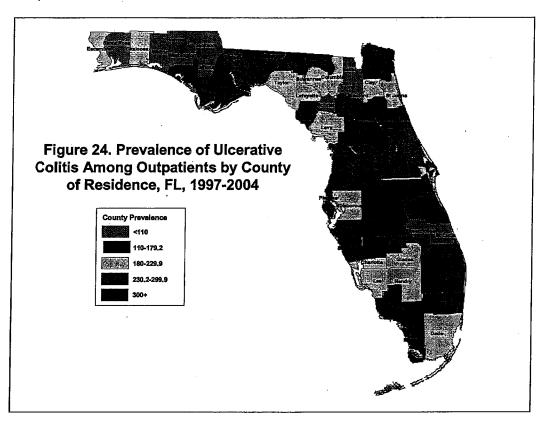
The percent of Crohn's disease patients with a colonoscopy was the highest among patients of other races (96 percent), and among patients with a private health insurance (95 percent). The percent of ulcerative colitis patients who had a colonoscopy was the lowest among Medicaid recipients (90 percent). (Figure 22)



Twelve counties had an eight-year overall prevalence of Crohn's disease of 140 per 100,000 persons or greater in Florida. These counties are Columbia, Union, Clay, Alachua, Flagler, Seminole, Pinellas, Manatee, Sarasota, Lee, Hendry, and Broward. (Figure 23) It is noteworthy that Union, Seminole, Pinellas, and Sarasota also had a high prevalence of Crohn's disease among inpatients. (Figure 15)



Thirteen counties had an overall prevalence of ulcerative colitis of 300 per 100,000 people or greater in Florida. These counties are Gulf, Leon, Jefferson, Citrus, Lake, Hernando, Seminole, Pinellas, Sarasota, Collier, Palm Beach, Broward, and Monroe. (Figure 24) Among these counties, Gulf, Citrus, Lake, Hernando, Sarasota, and Collier also had a high prevalence of hospitalization for ulcerative colitis.



Seminole, Pinellas, Sarasota, and Broward counties had high prevalence rates for both Crohn's disease and ulcerative colitis among ambulatory patients.

Sarasota was the only county that had a high prevalence for both Crohn's disease and ulcerative colitis among both inpatients and ambulatory patients.

BRFSS Survey

A total of 1,678 respondents answered the survey questions in the IBD module. Excluded from the analysis were 19 respondents who answered "don't know" or "not sure." Among the 1,659 respondents included in the final analysis, 63 reported that someone in their household was diagnosed with IBD. Three (4.8 percent) of 63 households had more than one person diagnosed with IBD.

BRFSS data suggested that 3.2 percent of all households have IBD patient(s), with 4.2 percent of households among Whites, 3.4 percent of households among Hispanics, 1.6 percent of households among Blacks, and 1.7 percent of households among other races.

There was no difference in the percent of having somebody with IBD between households with annual income less than \$50,000 and household with annual income of \$50,000 or more.

Among the 3,066 adults and 916 children within the 1,659 households, 66 persons were reported being diagnosed with IBD. Because the BRFSS survey did not ask for the age of individuals with IBD, the DOH team estimated that two of the people with IBD were children (under age 20), based on the age distribution of hospital discharge, and ambulatory care, data. The prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. These estimates were not weighted prevalence, which did not take into account of probability of survey respondents being included in the survey. A weighted prevalence will be available after CDC has completed the data weighting process.

Among survey respondents, 12 (18.2 percent) persons with IBD in 10 households were hospitalized in the past year. There was no difference in the percent of households with an IBD patient being hospitalized by race or by household income.

GI Physician Survey

The DOH received 113 completed survey questionnaires from GI physicians. The GI physicians who responded to the survey reported that 9,005 (7.3 percent) IBD patients were seen in the past 12 months among their 123,480 patients within that timeframe. Among IBD patients, approximately 14.2 percent were diagnosed in the past 12 months.

It was estimated that 40 percent of IBD patients were between the ages 20 and 45 years, and 30 percent were between the ages 45 and 65 years. IBD patients under age 20 years only accounted for approximately 10 percent.

Whites accounted for 93 percent of IBD patients; Blacks accounted for approximately 5 percent. Very few IBD patients were either Asian or other races.

Among IBD patients, females accounted for 51 percent and males for 49 percent. Approximately one quarter (22.4 percent) of patients had a family history of IBD, and one-eighth (12.2 percent) were hospitalized in the past 12 months.

The majority (94 percent) of IBD patients under the care of the responding physicians were enrolled in colon cancer surveillance.

IBD Patient Survey

The DOH received 27 completed survey questionnaires from IBD patients who voluntarily participated in the survey. The following are the results of the survey:

Age range of participants: 9 to 79 years

Age of diagnosis:

Age	<10	11-19	20-39	40-64	65 +
Percent	7.5	11	48	26	7.5

Average time living with IBD: 11.1 years

Gender: 78 percent Female 22 percent Male

Race/ethnicity: 96 percent Caucasian 4 percent Other

Jewish Decent: 33 percent yes, 63 percent no, and 4 percent unsure

Region of birth (within the US):

93 percent of respondents were born in the United States, of those:

Region	Southeast	Midwest	Northeast
Percent	28	4	68

Type of IBD:

Disease	Crohn's	Colitis	Crohn's & Colitis
Percent	56	40	4

Severity of symptoms:

78 percent of respondents reported their illness as active, of those:

Severity	Mild	Moderate	Severe
Percent	33	62	5

Family History: 18 percent had a family history; 78 percent reported no family history of IBD; and 4 percent unsure

Proximity to cattle:

- 19 percent lived near cattle prior to diagnosis.

Smoking status:

- 30 percent of respondents were current smokers, and 67 percent lived with a smoker prior to diagnosis. The percent of current smoking among IBD patients was higher than the 2004 state average prevalence (20.2 percent).

Colonoscopy:

- 56 percent had first colonoscopy due to IBD symptoms

Other medical conditions prior to diagnosis of IBD:

- 27 percent had serious medical illnesses
- 11 percent had psychological illnesses
- 37 percent were hospitalized
- 59 percent reported having surgeries

Of those reporting surgeries:

- 25.0 percent had appendectomies; 62.5 percent had tonsillectomies; 12.5 percent had other surgeries
- Other surgeries listed: liver transplant and c-section

Assessment of overall health:

- 18 percent said their health was poor

CONCLUSIONS

The Crohn's disease and ulcerative colitis epidemiologic study was conducted by the DOH in conjunction with the University of Florida, AHCA, and BCBS, under the guidance of the Advisory Committee. This study is a large population-based study that combined multiple sources of data that covers a majority of Florida's population. The data used in this study included 42,372,600 patient claim records in up to 10 years and survey data of approximately 2,000 households, providers, and patients.

This study was the first to provide state-specific data on IBD for Florida, in terms of estimating the prevalence of Crohn's disease and ulcerative colitis, the demographic characteristics of IBD patients, and major risk factors of the IBD.

Estimated prevalence of Crohn's disease and ulcerative colitis

The Prevalence

The population-based prevalence of Crohn's disease is estimated at 222 per 100,000 people, and the prevalence of ulcerative colitis at 307 per 100,000 people. These estimates were calculated based on age distribution of Florida's population and age-specific prevalence of Crohn's disease and ulcerative colitis of BCBS members.

The BCBS data showed that the prevalence of IBD among BCBS members, including inpatients and outpatients was for:

- Crohn's disease: 220 per 100,000 persons
- Ulcerative colitis: 300 per 100,000 persons
- Other colitis: 520 per 100,000 persons

BCBS data captured information on both hospitalizations (severe disease) and clinic visits (less severe disease). BCBS data were a good source in determining the prevalence of IBD because there is less disparity in access to health care among BCBS members. However, BCBS members are not a representative sample for overall Florida population, among which approximately 17 percent of people without a health insurance.

The estimates based on BCBS data were consistent with findings from previous epidemiologic studies in North America, which suggested population-based prevalence varied from 162 per 100,000 people to 199 per 100,000 people for Crohn's disease and from 170 per 100,000 people to 246 per 100,000 people.

The combined hospital discharge data and ambulatory patient data showed that, among patients treated in hospitals, the prevalence of:

- Any IBD: 2,737.8 per 100,000 people (or 2.74 percent)
- Crohn's disease and/or ulcerative colitis: 633.4 per 100,000 people
- Crohn's disease: 293.3 per 100,000 people
- Ulcerative colitis: 364.2 per 100,000 people

The prevalence of Crohn's disease and ulcerative colitis among inpatients and ambulatory patients was 32 percent and 19 percent, respectively, higher than the prevalence among BCBS members. The difference in prevalence might reflect a compositional difference of populations between hospital patients and BCBS members.

The prevalence of IBD among Medicaid recipients was lower than that among BCBS members the prevalence of patients with:

- Crohn's disease: 61 per 100,000 people.

- Ulcerative colitis: 26 per 100,000 people.

- Other colitis: 2,200 per 100,000 people.

The causes of low prevalence of IBD among Medicaid recipients were unknown based on the data of this study. More studies are needed to examine further the contribution factors of low prevalence of IBD, including access to health care and composition of the Medicaid population.

The BRFSS survey was unable to distinguish type of IBD due to the nature of a telephone survey of the general public. An overall prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. The BRFSS data represented population-based estimates, although the estimate was un-weighted and might carry large sample errors due to small sample size. The estimate was in line with other data in this study.

Number of Patients

It is estimated that approximately 35,500 Floridians have Crohn's disease and 49,000 have ulcerative colitis based on the estimated prevalence.

Hospitals in Florida served approximately 4,285 Crohn's disease patients and 5,450 ulcerative colitis patients either as inpatients or as ambulatory patients every year, accounting for approximately 12 percent and 11 percent of Crohn's disease and ulcerative colitis patients, respectively.

Demographic Characteristics

Age

The prevalence of Crohn's disease was relatively low among children and the elderly (age 70 years and older). The majority of IBD patients were diagnosed between the ages 11 and 40. The prevalence increased with age until age 50, then decreased with age.

The age-distribution might vary by population depending on the source of data. For example, the age-specific prevalence of ulcerative colitis among Medicaid recipients began to decrease among people age 50 years and older, which might reflect the fact that most Medicaid recipients were under age 50. On the other hand, the age-specific prevalence did not decrease until age 80 and older among hospital inpatients, among whom there were more elderly.

Sex:

The overall prevalence was very close between males and females, with a slightly higher prevalence among females than among males.

Both BCBS and Medicaid are population-based data that show a slightly higher prevalence of IBD among females than among males. However, the prevalence was slightly higher among males than among females for patients seen in hospitals, which might be due to the sex-distribution of hospital patients (more male patients than female patients are seen in hospitals).

Race/ethnicity:

Non-Hispanic Whites had a higher prevalence than non-Hispanic Blacks, Hispanics, and people of other races. Crohn's disease and ulcerative colitis occurred in all racial/ethnic groups.

Household Income:

No difference in prevalence by household income was found according to data from the BRFSS survey.

Type of Health Insurance:

Patients who were Medicare beneficiaries or who had private insurance had a higher prevalence rate of Crohn's disease or ulcerative colitis. Medicaid recipients had the lowest prevalence for both Crohn's disease and ulcerative colitis.

Type of medical insurance was the only variable available in the claim data and might be a surrogate indicator of socioeconomic status. The difference in prevalence might be attributable to the disparity in access to health care and the difference in race and age composition of the populations.

Residential County:

Based on hospital discharge data and ambulatory patient data, the following counties had high prevalence rates:

- Pinellas, Sarasota, and Seminole had a high prevalence of Crohn's disease.
- Citrus, Collier, Gulf, Hernando, Lake, and Sarasota had a high prevalence of ulcerative colitis.

Among BCBS members, those who resided in Glades and Wakulla counties had a high prevalence of Crohn's disease, and those who resided in Wakulla and Liberty counties had a high prevalence of ulcerative colitis.

Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

Risk factors

Previous epidemiologic studies on risk factors of Crohn's disease and ulcerative colitis suggested that although genetic factors might be strongly associated with IBD, environmental factors would explain most variations in the prevalence of IBD. The data in this study supported the findings from previous studies.

Genetic factors

A family history was found among approximately 20 percent of patients from the patient survey, physician survey, and BRFSS survey. Both claim data and survey data indicated that the majority of patients were non-Hispanic White. The patient survey data showed that nearly two thirds of IBD patients were born in the Northeast region of the U.S. and many of IBD patients were of Jewish descent.

The consistency of the finding of family history across surveys and aggregation of IBD in a population indicated a strong association between genetic factors and occurrence of IBD.

Environmental factors

Previous studies suggested several environmental risk factors, including cigarette smoking, consumption of milk, contact with cattle, and receiving certain types of surgery, might be associated with IBD. However, none of these environmental risk factors has been confirmed.

In this study, the DOH surveyed a small group of IBD patients for these potential risk factors. The survey found that the prevalence of cigarette smoking was higher than the state's average prevalence. Many patients were exposed to second-hand smoke, and had surgical procedures, such as tonsillectomy and appendectomy. However, because of the nature of the survey (a self-reported survey without a control group) and small sample size of the survey, no causal relationship could be established between these risk factors and IBD.

Recommendations for Future Studies

This study collected a great deal of data about IBD, and laid a foundation for future studies about IBD in Florida. To better assess IBD and to serve IBD patients in Florida, more studies are needed to:

- Increase sample size for the BRFSS survey to obtain a more accurate estimate of the population-based prevalence of IBD.
- Conduct a case-control study to identify risk factors of IBD.
- Develop an IBD patient voluntary registry through healthcare providers. This registry will
 provide data for a longitudinal follow-up study of IBD patients and many other studies on
 treatment, outcome, and patient's quality of life.

ATTACHMENTS

Attachment 1: GI PHYSICIAN SURVEY

A Survey about Inflammatory Bowel Disease Patients

The purpose of this survey is to collect data on inflammatory bowel disease patients, particularly for those who may not have been hospitalized. All data collected from this survey will be kept strictly confidential. Please give your <u>best approximation</u> for the following questions.

	<20 yrs	20-44 yrs	45-64 yrs	65 yrs and older
# Patients				
Race	White	Black	Asian	Other
# Patients	Wille	Black	Asian	Other
Sex	Male	Female	_	
# Patients			_	
Ethnicity	Hispanic	Non-Hispanic	7	
# Patients				
Among the	ose IBD patient	s, how many have b	een hospitalized	for IBD in the past 12 months
		s, how many have b	-	-
How many	of your patient	ts with IBD report a	family history o	-
How many	of your patient IBD patients, a	ts with IBD report a	family history o	f the illness? nin the past 12 months?
. Among all . Do you ent	of your patient IBD patients, a er your IBD pa	ts with IBD report a	family history or diagnosed with cancer surveillan	f the illness? nin the past 12 months? nce program?

Attachment 2: IBD PATIENT SURVEY

Inflammatory Bowel Disease Patient Questionnaire

Dear Respondent: As you may be aware, the Florida Department of Health is conducting a study to uncover the potential role of genetic and environmental risk factors associated with Inflammatory Bowel Disease (as mandated by House Bill 869, also known as the "Crohn's & Colitis Disease Research Act"). This is a short survey designed to evaluate potential genetic and environmental exposures for patients with IBD. If you have been diagnosed with IBD, please answer the following questions to the best of your ability. You are not obligated to answer every question, though we kindly ask that you answer as many questions as you feel comfortable in giving a response. All information provided will remain confidential. We are not asking for any personal identifiers (such as name, date of birth, or social security number), to ensure that your information is also anonymous. You are an invaluable resource in the development of this area of research. Your time, effort, and comments are greatly appreciated. If you have any questions or comments about this study, please contact the Crohn's & Colitis Research Coordinator at the Florida Department of Health, (850) 245-4444 extension 2424.

- 1. Current age:
- 2a. Age at Diagnosis of Inflammatory Bowel Disease:

 1) 10 or under 2) 11-19 3) 20-39 4) 40-64 5) 65 or older
- 2b. Time you have lived with the disease in years (or months if less than 1 year):
- 3. Gender: 1) Male 2) Female
- 4. Ethnicity: 1) Caucasian 2) African American 3) Asian 4) Hispanic 5) Other:
- 5. Are you of Jewish descent? 1) Yes 2) No 3) Partly 4) Don't know/unsure
- 6a. Do you have:
- 1) Ulcerative Colitis 2) Crohn's Disease 3) Both CROHN'S DISEASE & ULCERATIVE COLITIS 4) Unsure
- 6b. Where is your disease located?
 - 1) small intestine 2) large intestine 3) both small and large intestines
 - 4) other 5) unsure
- 6c. Currently, is your disease active? 1) No 2) Yes

 If yes, would you say your symptoms are: 1) mild 2) moderate 3) severe

7a. Do you have a family member who is also diagnosed with an IBD?1) No 2) Yes
7b. If yes, please select all who have been diagnosed: 1) Mother 2) Father 3) Brother 4) Sister 5) Your child/children 6) Other:
8a. Were you born in the United States? 1) Yes 2) No
8b. If yes, what area of the United States were you born?1) NorthEast 2) SouthEast 3) Midwest 4) NorthWest 5) SouthWest
9. Before you were diagnosed with an IBD, did you live near cattle? 1) Yes 2) No
10. Before you were diagnosed with an IBD, did you smoke cigarettes regularly, meaning on most or all days?
1) Yes-# of years: 2) No
11a. Before you were diagnosed with an IBD, did the other people living in your residence smoke cigarettes? 1) No 2) Yes
11b. If yes, please list the number of years you lived in this residence prior to your diagnosis:
12a. Did you receive a colonoscopy before you were diagnosed with an IBD?1) Yes 2) No 3) Unsure
12b. If yes, was your first colonoscopy a result of your IBD symptoms?1) Yes 2) No 3) Unsure
13a. Before you were diagnosed with an IBD, did you have any of the following:
Medical illnesses Psychological illnesses Medical hospitalizations Surgeries 1) Yes 2) No 3) Don't know/unsure 1) Yes 2) No 3) Don't know/unsure 1) Yes 2) No 3) Don't know/unsure 3) Yes 2) No 3) Don't know/unsure
13b. Before you were diagnosed with an IBD, did you have any of these procedures: Appendectomy 1) Yes 2) No 3) Don't know/unsure Tonsillectomy 1) Yes 2) No 3) Don't know/unsure Other (please list):
14. In general, would you say your health is: 1) Excellent 2) Good 3) Average 4) Poor



Health Care General Committee

Wednesday, March 15, 2006 9:00 AM – 11:00 AM 306 HOB

COMMITTEE MEETING PACKET

Revised

ADDENDUM "A" (03/14/2006; 5:00 PM)

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 621

Health Maintenance Organizations

SPONSOR(S): Grimsley and others

TIED BILLS:

IDEN./SIM. BILLS: SB 94

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Brown-Barrios	Brown-Barrios
2) Insurance Committee		_	
3) Health & Families Council			
4)			
5)			
		-	

SUMMARY ANALYSIS

The laws regulating health maintenance organizations (HMOs) provide for the regulation of fiscal intermediary services organizations (FISOs). The law is designed to protect funds received from an HMO and held by entities which have an obligation to distribute those funds to health care providers who contract with the HMO. This is primarily done by requiring those entities to apply for registration and to post a fidelity bond and a surety bond with the Office of Insurance Regulation (OIR). The bill revises the definition of who must be registered as a FISO by deleting the exemption for entities that are owned, operated, or controlled by certain licensed entities. As revised, only the licensed entities themselves would be exempt, including hospitals, authorized insurers, third party administrators, prepaid limited health service organizations, and HMOs. Also, the current exemption for physician group practices would be limited to group practices providing services under the scope of licenses of the members of that group practice.

Currently, HMOs remain responsible for compliance with statutory requirements related to prompt payment. treatment authorization, and adverse determinations, if the HMO transfers its payment obligations under a health care risk contract to a licensed administrator. The bill would broaden this responsibility to include an HMO transferring its payment obligations to any entity, not just licensed administrators, but would maintain exceptions for contracts with providers, group practices, and hospitals. The bill also deletes the condition that the payment obligations must be transferred under a health care risk contract, so that the HMO would remain responsible, regardless of the type of contract, if the HMO transfers its obligations to pay any provider for claims arising from services provided to any subscriber of the HMO.

This bill will not have any fiscal impact on the public sector and should have limited fiscal impact on the private sector.

If enacted the bill act takes effect October 1, 2006.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0621.HCG.doc

DATE:

3/13/2006

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government -- Health maintenance organizations would have broader liability for interest payments, fines, and other sanctions for violations of laws related to prompt payment, treatment authorizations, and adverse determinations, if the HMO transfers its payment obligations to another entity, potentially impacting premiums for HMO coverage.

Ensure Lower Taxes -- Entities which are no longer exempt from registration with OIR as a fiscal intermediary service organization would be subject to the expense of obtaining a surety bond and fidelity bond.

B. EFFECT OF PROPOSED CHANGES:

The bill revises the definition of a fiscal intermediary services organization by narrowing certain exemptions from the current definition. By doing so, certain entities that are currently exempt would be required to be licensed as a FISO. Specifically, the bill deletes the exemption for entities that are owned, operated, or controlled by certain licensed entities, so that only the licensed entity itself would be exempt. These licensed entities include hospitals licensed under ch. 395, F.S., insurers licensed under ch. 624, F.S., third party administrators licensed under ch. 626, F.S., prepaid limited health service organizations licensed under ch. 636, F.S., and health maintenance organizations licensed under ch. 641, F.S. Also, the current exemption for entities owned, operated, or controlled by physician group practices is revised to be limited to physician group practices, as defined in s. 456.053(3)(h), F.S., providing services under the scope of licenses of the members of the group practice. In other words, a physician group practice providing fiscal intermediary services to members outside of that group practice would not be exempt from licensure as a FISO.

The bill broadens the responsibility for an HMO to remain responsible for violations related to prompt payment, treatment authorization, and adverse determinations, if the HMO transfers its payment obligations to another entity. The bill would broaden this responsibility to include an HMO transferring its payment obligations to any entity, not just to a licensed administrator under s. 626.88, F.S. This would include transfer of payment obligations to a FISO or possibly to an unregulated entity that may not meet the definition of an administrator or FISO. However, the bill would maintain the current provisions that an HMO is not responsible for violations related to prompt payment if payment obligations are transferred to any provider or group practice, as defined in s. 456.053, F.S., providing services under the scope of the license of the provider or the members of the group practice, or to a hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

The bill also deletes the reference to an HMO transferring its payment obligations through a health care risk contract as a condition for the HMO to remain responsible for violations related to prompt payment. Therefore, regardless of the type of contract, if the HMO transfers to any entity the obligations to pay any provider for any claims arising from services provided to or for the benefit of any subscriber of the HMO, the HMO would remain responsible for the specified violations.

BACKGROUND

Regulation of Health Maintenance Organizations

OIR regulates health maintenance organization solvency, contracts, rates, and marketing activities under part I of chapter 641, F.S., while the Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of chapter 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA. Any entity that is issued a certificate of authority and that is otherwise in compliance with the licensure provisions

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under part I may enter into contracts in Florida to provide an agreed-upon set of comprehensive health care services to subscribers.

Fiscal Intermediary Services Organizations (FISOs)

Legislation in 1997 amended the HMO laws to provide for the regulation of FISOs. At that time, some health care professionals were contracting with unregulated entities to collect payments from HMOs on the providers' behalf and to distribute those funds to the contracting health care providers. There were reported cases of misappropriation of funds by such entities, with no apparent recourse to regulatory agencies. Essentially, the law is designed to protect funds received from an HMO and held by entities which have an obligation to distribute those funds to medical professionals who contract with the HMO. This is primarily done by requiring those entities to apply for registration and to post a fidelity bond and a surety bond with OIR. A fiscal intermediary services organization is defined as:

[A] person or entity which performs fiduciary or fiscal intermediary services to health care professionals who contract with health maintenance organizations, other than a fiscal intermediary services organization owned, operated, or controlled by a hospital licensed under chapter 395, an insurer licensed under chapter 624, a third party administrator licensed under chapter 626, a prepaid limited health service organization licensed under chapter 636, a health maintenance organization licensed under chapter 641, or physician group practices as defined in s. 456.053(3)(h).²

The term fiduciary or fiscal intermediary services means:

[R]eimbursements received or collected on behalf of health care professionals for services rendered, patient and provider accounting, financial reporting and auditing, receipts and collections management, compensation and reimbursement disbursement services, or other related fiduciary services pursuant to health care professional contracts with health maintenance organizations...³

The above definition of a FISO exempts physician group practices, but it is not clear that this exemption is limited to providing fiscal intermediary services only to members of that group practice, though that may be the intent. This appears to be a broader exemption than a similar exemption for physician group practices from licensure as an administrator in s. 626.88(1)(o), F.S. (See, Administrators, below.) That statute limits the exemption for physician group practices to providing services under the scope of the license of the members of the group practice. The definition of a FISO also exempts organizations owned, operated, or controlled by various licensed entities, such as hospitals, insurers, third-party administrators, HMOs, etc. In contrast, the exemption from licensure as an administrator includes licensed insurers, HMOs, and certain other entities, but does not exempt subsidiaries or other independent organizations that are owned, operated, or controlled by such licensed entities.

The express legislative intent of the statute is to ensure the financial soundness of FISOs. A FISO which is operated for the purpose of acquiring and administering provider contracts with managed care plans must secure and maintain a fidelity bond and a surety bond. As currently required, a fidelity bond must be maintained in the minimum amount of 10 percent of the funds handled by the FISO during the prior year or \$1 million, whichever is less, but not less than \$50,000. This bond protects the

³ Section 641.316(2)(a), F.S.

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¹ s 641.316, F.S.

² s. 456.053(3)(f), F.S., provides, "Group practice" means a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:

^{1.} In which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

^{2.} For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and

^{3.} In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.

FISO from loss due to dishonesty of its employees. A surety bond must also be maintained in the minimum amount of 5 percent of the funds handled by the FISO during the prior year or \$250,000. whichever is less, but not less than \$10,000. The surety bond protects against misappropriation of funds within the FISO's control or custody.

A FISO registering with OIR must meet certain application requirements of chapter 641, F.S. that apply to HMOs. These require that a FISO provide OIR with a list of the names, addresses and official capacities of the persons who are responsible for the operations of the company, including officers, directors, and owners of more than 5 percent of the common stock of the company. The listed persons must fully disclose all contracts or arrangements between them and the company, including any conflicts of interest, and must submit autobiographical statements, fingerprints, and an independently performed background report. In general, receiving authority to operate as a FISO is conditioned on OIR being satisfied that the ownership, control and management of the entity is competent and trustworthy, and possesses managerial experience that would make the proposed operation beneficial to its constituents.

There are currently 15 active FISOs registered with OIR. Once a FISO is registered, there is generally no regulatory activity other than periodic review of the surety bonds and fidelity bonds to determine if the amounts are adequate relative to the amount of funds handled annually by the FISO, as required by statute.

Regulation of Third Party Administrators

A person who acts as an administrator, more commonly referred to as a "third party administrator "or TPA, must be licensed by OIR. As defined:

[A]n administrator is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage...or any person who, through a health care risk contract as defined in s. 641.234 with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers....5

The two definitions for a FISO and an administrator overlap to some extent, by encompassing persons or entities that provide billing and collection services to HMOs on behalf of health care providers. However, the definition for an administrator includes authority to engage in claims adjudication or collection of premiums for a health insurer or HMO, which activities are not authorized by the FISO statute. Administrators that are licensed by OIR are exempt from the requirement of being registered as a FISO.

The requirements for administrators under ss. 626.88-626.894, F.S., are more extensive than the regulation of FISOs. For example, an administrator must make its books and records available to OIR for examination, audit, and inspection and must maintain its business records for five years.⁶

Administrators are also required to file annual financial statements with OIR. However, the fidelity bond requirement may be less for an administrator than a FISO, depending on the amount of funds handled, and a separate surety bond is not required for an administrator as it is for a FISO.8 Administrators must have a written agreement with an insurer containing specified provisions. The insurance company, and not the administrator, must be responsible for determining the benefits, rates

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ss. 641.21(1)(c) and 641.22(6), F.S.

s. 626.88(1), F.S.

s. 626.884, F.S.

s. 626.89, F.S.

⁸ s. 626.8809, F.S., requires an administrator to maintain a fidelity bond of at least 10 percent of the amount of funds handled or managed annually, but not greater than \$500,000, unless OIR, after notice and opportunity for hearing, requires an amount in excess of \$500,000 but not more than 10 percent of the amount of the funds handled or managed annually. STORAGE NAME: h0621.HCG.doc PAGE: 4

underwriting criteria, and claims payment procedures. A payment to the administrator of any premiums on behalf of the insured are deemed to have been received by the insurer and all premiums collected by an administrator on behalf of an insurer must be held by the administrator in a fiduciary capacity. If an administrator is collecting premiums for more than one insurer, the administrator must keep records clearly recording each insurer's accounts.

The administrator law requires that a person who provides billing and collection services to HMOs on behalf of health care providers must comply with s. 641.3155, F.S., the prompt payment statute, and s. 641.51(4), F.S., which requires that only a Florida licensed allopathic physician or osteopathic physician may render an adverse determination regarding a service provided by a physician licensed in the state and specifies procedures that must be followed.¹⁰

Payment Documentation by FISOs and Administrators

Legislation in 1999 amended both the FISO and administrator laws to require that payment by a fiscal intermediary to a health care provider include specified information. This was in response to complaints by health care providers that claims payments by FISOs did not delineate sufficient information for the providers to reconcile their records as to which claims were being paid. The law now requires that for a capitated health care provider, the statement must include the number of patients covered by the contract, the rate per patient, total amount of payment, and the identification of the plan on whose behalf the payment is made. For a noncapitated health care provider, the statement must include an explanation of services being reimbursed, including the patient name, date of service, procedure code, amount of reimbursement, and plan identification. The law does not define capitated or noncapitated, but is understood to distinguish those contracts that provide for a specified payment rate per patient for all services or specified types of services, and those contracts that, instead, provide payment on a fee-for-service basis.

HMO Responsibility for Violations of Prompt Pay Law if Payment Obligations are Transferred A law enacted in 2002 holds HMOs ultimately responsible for compliance with certain statutory requirements related to prompt payment, treatment authorization, and adverse determinations, if the HMO transfers its payment obligations to a licensed administrator. But the law apparently does not hold an HMO responsible for compliance with such requirements if it transfers its payment obligations to an entity other than a licensed administrator.

Specifically, this law provides that if an HMO, through a health care risk contract, transfers to any entity the obligations to pay a provider for any claim arising from services provided to a subscriber, then the HMO remains responsible for any violations of three specified statutes:

- Section 641.3155, F.S., which are the prompt payment requirements;
- Section 641.3156, F.S., which requires HMOs to pay claims for treatment if a provider follows the treatment authorization procedures and receives authorization; and
- Section 641.51(4), F.S., which requires that only a Florida licensed allopathic physician or
 osteopathic physician may render an adverse determination regarding a service provided by a
 physician licensed in the state and specifies procedures that must be followed.

The following definitions apply to administrative, provider, and management contracts:

- Health care risk contract means:...a contract under which an entity receives compensation in exchange for providing to the health maintenance organization a provider network or other services which may include administrative services.¹³
- Entity means:...a person licensed as an administrator under s. 626.88, F.S., and does not include any provider or group practice under s. 456.053, F.S., providing services under the scope of the license of the provider or the members of the group practice. The term does not

¹³ s. 641.234(4)(b)1.

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ss. 626.8817 and 626.882, F.S.

¹⁰ s. 626.88, F.S.

th. 99-275, L.O.F.; ss. 626.883(6) and 641.316(2)(a), F.S.

² ch. 2002-389, L.O.F.; s. 641.234(4), F.S.

include a hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

The enactment of the prompt payment requirements and persistent efforts by health care provider groups to document complaints and seek enforcement has resulted in OIR conducting examinations and sanctions against HMOs violating these provisions.

Senate Committee Staff Interim Project

The "BACKGROUND", provided above, summarizes the report and findings in the 2005 Senate Banking and Insurance Committee staff interim project, Determining the Sufficiency of Regulation of Third-Party Administrators and Fiscal Intermediary Services Organizations (2005-109). The interim project made the following recommendations:

- Expand the requirements of s. 641.234(4), F.S., to hold a health maintenance organization. responsible for statutory requirements related to payment to health care providers if the HMO transfers to any entity the obligations to pay providers. The current law may limit this liability to HMO contracts with licensed administrators and limit this responsibility to violations of only certain statutes.
- Narrow the exemption from registration as a FISO for a physician group practice in s. 641.316. F.S., to physician group practices providing fiscal intermediary services to members of the group practice.
- Narrow the exemption from registration as a FISO for licensed insurers, HMOs, administrators. hospitals, and prepaid limited health service organizations to those entities themselves, rather than any entity owned operated, or controlled by such licensed entities.
- Alternatively, consider repealing the FISO statute and require entities to be licensed as third party administrators if they provide fiscal intermediary services to providers under contract with HMO.

C. SECTION DIRECTORY:

Section 1. Amends s. 641.316, F.S., relating to the definition of a fiscal intermediary services organization.

Section 2. Amends s. 641.234, F.S., relating to administrative, provider, and management contracts.

Section 3. Amends s. 626.88, F.S., relating to insurance administrators.

Section 4. Provides that this act takes effect October 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

• • •		
	None	

2. Expenditures:

1. Revenues:

None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

¹⁴ s. 641.234(4)(b)2., F.S.

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2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health maintenance organizations would have broader liability for interest payments, fines, and other sanctions for violations of laws related to prompt payment, treatment authorizations, and adverse determinations, if the HMO transfers its payment obligations to another entity, potentially impacting premiums for HMO coverage. Health care providers may benefit by greater compliance with such laws or by regulatory sanctions for non-compliance under such arrangements.

Entities which are no longer exempt from registration with OIR as a fiscal intermediary services organization would be subject to the expense of obtaining a surety bond and a fidelity bond.

D. FISCAL COMMENTS:

None

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, does not appear to reduce the authority that counties or municipalities have to raise revenue in the aggregate, and does not appear to reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None

B. RULE-MAKING AUTHORITY:

None

C. DRAFTING ISSUES OR OTHER COMMENTS:

None

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

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Total Hospital Charges for IBD Patients 1997-2004

